THE PUBLIC'S HEALTH

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THE LAW

IN THE

21ST CENTURY:

A Partnership Conference

on

Public Health Law

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AMERICAN SOCIETY OF
LAW, MEDICINE & ETHICS

Fall 2002

Dear Society Members and Journal Subscribers:

On June 17–19, 2002, the American Society of Law, Medicine & Ethics, in partnership with the Centers for Disease Control and Prevention and the Department of Health and Human Services, convened a major conference entitled "The Public's Health and the Law in the 21st Century." More than 500 individuals from all of the fifty states assembled in Atlanta, Georgia, to engage in both plenary and concurrent sessions devoted to all aspects of public health and the role that law plays in promoting and sustaining a healthier population. The audience was truly multidisciplinary—and included lawyers, physicians, state legislative members, public health officers, nurses, bioethicists, and academics. This supplement seeks to capture the essence of the plenary and concurrent sessions of the program.

The conference collaborators wish to acknowledge the generous unrestricted funding from the Robert Wood Johnson Foundation and the Milbank Memorial Fund and the Sloan Foundation. The American Society of Law, Medicine & Ethics acknowledges the creative work of the program planning committee, the authors of the articles included in this supplement, and the dedication of the extraordinary conference faculty.

We also extend our special thanks to each of the following for their exceptional support for the conference and the conference proceedings: Julie Gerberding, MD, MPH, Director of CDC; Martha Katz; Kathy Cahill, MPH; Deborah Jones; Edward Baker, Jr., MD, MPH; James Marks, MD, MPH; Richard Jackson, MD, MPH, and other colleagues at CDC for their financial and technical support for planning the conference. Finally, we thank Sherry Everett Jones for serving as Editor-in-Chief and Richard Goodman for serving as the Associate Editor of the proceedings and for their enthusiastic support for the proceedings and the conference.

Sincerely,

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Preface

Sherry E. Jones, Richard A. Goodman, Ernest L. Martin, Nancy L. Kluisza

This supplement to the *Journal of Law, Medicine & Ethics* is the proceedings of the conference *The Public's Health and the Law in the 21st Century* held in Atlanta, Georgia on June 17–19, 2002. The conference was co-sponsored by the American Society of Law, Medicine & Ethics and the Centers for Disease Control and Prevention. In addition, the conference planning committee (see Appendix A) and the many funding and collaborating organizations (see Appendix B) were critical to the conference's success.

This national conference was the first of its kind, bringing together more than 500 participants with a wide range of expertise in public health, the law, and related disciplines. Participants included state and local public health leaders and practitioners, elected and appointed public policy makers, physicians and attorneys working in public health, and researchers and educators in public health law.

The goal of the conference was to improve the understanding of the critical role law plays in protecting the public's health, offer cutting-edge perspectives on the intersection of public health and law, apply science-based information about law to public health policymaking and practice, and form partnerships to shape and use legal tools for improved public health. Panels comprising legislators, policy makers, practitioners, and legal counsel provided participants a unique opportunity to learn how a cross-disciplinary approach can strengthen law's contribution to improved public health.

These proceedings capture both the spirit and the substance of the meeting. The goal of the editors was to ensure an accurate record of the conference while retaining the unique expression of each contributor. These proceedings first present papers from the plenary sessions. These papers address issues that are both cross-cutting and central to all those who shape, implement, and interpret public health laws and policies. Following the plenary papers are articles that address specific areas of public health law of high importance, including, for example, public health legal preparedness; models for prevention systems; building healthy communities; safe water, food, and air; tools to prevent infectious disease; preventing injuries and abuse; and emerging issues in public health and law.

These proceedings would not have been possible without the hard work and dedication of many individuals. In particular, we thank Ben Moulton, Executive Director of the American Society of Law, Medicine & Ethics, Kelly McDonald, Managing Editor of the *Journal of Law, Medicine & Ethics*, Victoria Stratton, Executive Assistant, *Journal of Law, Medicine & Ethics* and Assistant Editor, American Society of Law, Medicine & Ethics, and Anthony D. Moulton, Director of the CDC Public Health Law Program for their support in the development of the proceedings. We thank each of the proceedings authors who were dedicated to working together to produce manuscripts that captured the

substance of each conference session. We would like to add special thanks to the Robert Wood Johnson Foundation for its generous educational grant to help fund the conference, the Milbank Memorial Fund for its generous assistance in planning the conference, and the members of the conference planning committee, all of whom made the idea for this first-of-its-kind conference become a reality. Finally, we thank the many Centers for Disease Control and Prevention programs that provided financial and technical support for sessions throughout the conference (Appendix B).

We hope these proceedings provide a means for conference participants and other readers to strengthen public health practices.

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Conference Welcoming Remarks

Julie Gerberding, Director, Centers for Disease Control and Prevention

It is an honor to be here. Any time a physician gets in front of a room full of attorneys, one is a little bit nervous. This is an historic moment. While I was preparing my remarks, I was looking through the books that are available here, noticing the titles, and I saw things written on bioethics, health policy, bioterrorism, industrial agriculture, food safety, environmental justice, reproductive health, and so on and so forth.

There are public health officials here, attorneys, academicians, private sector organizations, legislators, and other decision-makers. This has got to be one of the most diverse groups of people coming together around the most diverse set of ideas that CDC has ever hosted. This kind of diversity, sharing the conference's dual focus on legal preparedness and partnerships, might be described by the term *consilience*—a lumping together of ideas across a widely disparate group of disciplines, focuses, and themes for the purpose of bringing to fruition a new field of public health, legal preparedness. The challenges are great but the opportunities are also exciting, and I do really see this as an historic moment and a very suitable way to start the new millennium.

Now, let me just say a few things about why this meeting is important, why are we here and, at least from the CDC perspective, what is the justification for taking you all away from the work place and asking you to focus on this conference? We know that our children will live about 30 years longer than our great-grandparents. Many people attribute this increase in lifespan to things like better medical care, antibiotics, and so forth. But actually, only about 25 of the 30 years in increased life expectancy that Americans are experiencing can be attributed to those medical advances. Most of these years can be attributed to immunizations, food safety, water safety, and overall improved living conditions.

Law was critical to each of these public health achievements. For example, compulsory immunization came about as a result of a United States Supreme Court ruling in Jacobson v. Massachusetts. The Pure Food and Drug Acts of 1906 and the Safe Drinking Water Act of 1974 have accounted for improvements in food and water safety. Other legal developments to improve public health include the Surgeon General's warning notices on cigarette packs and restrictions on tobacco advertising, mandated seat belt use, product safety laws, fluoridation ordinances and the Federal OSHA standards.

Laws create public health agencies and empower them, but laws in and of themselves also create standards and regulations and a framework for improving the health and safety of Americans. There are many challenges that we must face in the next decade and in the next millennium. The attacks of 9/11 certainly taught us that we need to be prepared for threats in the domestic framework as well as the international framework. Terrorism

is here to stay for the foreseeable future, and I think it's having a profound effect on our lives. It also created a new discipline, and that is the discipline of forensic epidemiology, where we learn how to conduct investigations from an epidemiologic public health perspective side-by-side with investigators from the law enforcement field.

Even if we didn't have to contend with terrorism, we are still facing great challenges in the next decades. The influenza pandemic of the early part of the last century must portend the potential for an influenza pandemic in the next century. We can never keep up with the microbes and their capacity to escape immunization or anti-microbial therapy, and there are a whole host of other emerging infectious disease threats that we learned about, even in the last few years—Hantavirus, Ebola virus, hemorrhagic fevers, and so forth.

So, our infectious disease challenges will enlarge, but our challenges are not limited to the infection component, of course. Think about what's happening with our population demographics. We are aging. The increase in people over 65 anticipated in the next 15 to 20 years is going to have a profound impact on our whole social structure, our medical system, and our public health system.

We also face major challenges in the arena of chronic diseases. Some of these chronic diseases are preventable by means of legal action in such areas as restricting tobacco use, providing opportunities for exercise in schools, and controlling activities that do not support reproductive health or sexual health or psychological health in the nation. They're great challenges, and we are not anywhere near accomplishing them.

In this context, I should also mention health disparities. We still live in a nation where we have wide disparities in access to care and quality of care. A very poignant example is the major disparities in infant mortality experienced across races in this country. We have to meet these challenges if we're going to be successful in continuing the improvements in the standard of living and the quality of life that we have enjoyed in the last century.

These are going to take major interfaces, a lot of consilient thought, a lot of conferences, but also they're going to take good public health law. Public health law must be modernized if we're going to be successful. Many of our laws are out of date and they have not been tested in the crucible of real public health emergencies. Far too few public health practitioners have access to the training and education needed to use their legal powers. But the need is bi-directional: far too few lawyers who serve public health agencies understand how to practice what CDC people refer to as preventive law—using law as a tool to enhance the public's health rather than to defend against actions. And far too few public health workers understand how to use their legal powers to support protective public health efforts. *The Public's Health and the Law in the 21st Century* provides an opportunity for individuals representing diverse disciplines to come together to address true public health law preparedness.

So, I think what we need to do over the next months or years is to come together and address what really would constitute true public health legal preparedness, and there are four major components to this that would comprise a comprehensive strategy. First of all, our communities, our states and our nation must have the legal authority necessary to carry out essential public health services. Second, public health officials, their staff and their legal counsel should have access to the training and educational opportunities that help them develop the skills and the capacities to fulfill this mission. Third, public policy makers, including legislators, governors, and their counterparts in city and county government, must have access to science-based information about which laws are effective and appropriate in addressing a specific health problem. You don't always think about research or the need for a scientific basis for law, but clearly in the arena of public health law, at least, this is absolutely essential. And finally, probably new institutions are needed to support these activities. There is not an association of public health law or public health attorneys, and I think that this meeting, this first opportunity to come together in

such a large framework, might be the impetus for a new organization or at least a new network and coalition of folks interested in public health law, drawing upon the opportunities for consilience that I've already mentioned.

The success to which we accomplish the challenges of the next decade or millennium really will be measured not by what's gone before us, but how well we build to prepare for the public health challenges that we cannot predict. This is really the ultimate criterion for preparedness and, in order to meet it, we must build a system of public health preparedness that is effective, resilient, and flexible. These are themes that really penetrate the whole public health system, not just the law. The great American abolitionist, Wendell Phillips, famously said, "The price of liberty is eternal vigilance." One price of freedom from disease is full public health preparedness for whatever challenges the future holds for us.

Legal preparedness is an indispensable component of this preparedness, and I'm very pleased to be in the same room with so many colleagues from so many disciplines who are committed to that goal. I believe your efforts will be the first giant step forward, and I look forward to watching the progress unfold. You have important work to do, and we are very, very grateful for the time and interest that all of you have brought to the table to bear on this important area. So, thank you very much, and good luck.

Conference Welcoming Remarks

Thurbert Baker, Attorney General, State of Georgia

Good morning. Welcome to the great State of Georgia, for those of you who do not live here, As I look out over this room, I am truly, truly amazed. I understand there are 50 states represented here this week for the conference, and we also have at least a half-dozen countries represented here.

What a grand gathering of people, really from all over the world, to come and talk about an issue that is near and dear to us all. I think by the overwhelming attendance that we see here this morning, this issue of the law and public health and how that relationship affects our daily lives is of interest to a great many people. You know, one of the most profound developments, I believe, that we will witness during our lifetimes will be the evolution of that interrelationship between public health and public law.

I contemplated this interplay last evening as I searched for what might be the genesis of this relationship, trying to determine the route to what we see going on today. My attention was drawn to Article I of the United States Constitution, where we see a reference to the interplay of health and law. I'm always fascinated by how the forefathers of this great republic over 200 years ago had the vision and the foresight to see what might be coming down the road. They had the ability to set the priorities for a country and to lay out the route that has served us so well over the years.

And I noticed in Article I of the U.S. Constitution the language that said, "We the people of the United States, in order to form a more perfect union, promote the general welfare of the people and, thereby, establish this great Constitution." And I thought to myself, "How prophetic that over 200 years ago, as they gathered in Philadelphia, Pennsylvania when, quite frankly this country was just barely three million people, they had the vision and the foresight to understand that the general welfare of the people was first and foremost among the responsibilities of any great government." We've seen in recent days I think just how prophetic that has become.

In the aftermath of 9/11, I don't think there is any question that is more pronounced on the lips of everyone here in this country than what we do to protect the United States and its citizens—to protect ourselves on many different fronts but, in particular, to protect people in this country from acts of bioterrorism. I had a great opportunity in the aftermath of 9/11 to do something that we probably should have done a long time ago, and that was to do a top to bottom analysis of all of the laws in this state that protect the citizens, in both the law and health arenas. It is going on, quite frankly, all over the country, that sort of analysis, not just at the state level, but at the federal level as well as we come to grips with the aftermath of 9/11. It gives you some idea of how the law relates to public health and how we must make sure that

they are both working in sync to provide for the general welfare of the people of this country.

Several years ago I had the great opportunity to work with the nation's Attorneys Generals through the National Association of Attorneys General, to develop and to agree upon one of the most profound agreements/settlements in the history of this country. It was a multi-billion dollar settlement, over $200 billion, in the area of tobacco and tobacco usage. As many of you know, it was a historical landmark occasion as the nation's Attorneys Generals came together with the industry to develop what I think will be one of the most far-reaching documents in the history of America. But it was all related to the public's health. While there was a lot of discussion and a lot of talk about the size of the settlement, I will tell you that it was all driven by public health and what we need to do to protect the health of people in this country.

We talk a great deal within the association and, certainly, right here in this state about the issue of domestic violence. It is an area that is a public health issue, because it is a silent killer, one in which women and children are being impacted greatly throughout the vast reaches of this country. It is a problem that affects not only Small Town, U.S.A., but metropolitan areas all over America. Right here in Georgia we saw a tremendous increase over the years in the number of acts of domestic violence. It is not uncommon for someone to get killed during a domestic dispute.

Several weeks ago, I appeared before the U.S. Senate, the Senate Judiciary Committee. I spoke to that Committee about the need to make sure that the domestic violence laws of this country are strong because we need the national presence to make sure that this very critical health issue is one that is addressed and is addressed at all levels of government. I also urged the Senate Judiciary Committee to work not only on a national level, but on a state level by providing the appropriate dollars that are needed for this very, very important mission.

I also read, and I'll share this last thought with you, a very interesting report. It was a report that was generated by the Council on Foreign Relations, one of the most respected think tanks in the country, and the Milbank Memorial Fund. It was about how important health is in regards to foreign policy. And I said to myself, "What an interesting twist that is," and I examined what the connection was. Clearly, the result and the underpinning of it all was the idea that supporting health worldwide will indeed enhance U.S. National Security and increase the prosperity at home and abroad, and really promote democracy in some of the emerging countries around the world.

How far we have come since the framers of the constitution over 200 years ago saw that connection between public health, the public's welfare and public law! How prophetic they must have been, and I want to remind you as you work together this week on these very, very important issues, how important your work will be. Never underestimate the value of this issue. Never underestimate how it will evolve during the 21st century, and always remember that you will have a great part in where these issues go.

Franklin Delano Roosevelt, who was one of our great Presidents and one who had the good foresight to spend a great deal of his time here in Georgia, had these words for the American people. He said, "The only limitation to our realization of tomorrow will be our own doubts of today." There should be no doubts in your mind as you gather this week at this great, great conference in the greatest state in all of America that you will indeed make a tremendous difference, and that what you do here today will make a difference for future generations of Americans. Thank you so very much.

Partners in Public Health Law: Elected Officials, Health Directors, and Attorneys

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Abstract

The partnership that has developed over the years between elected officials, health directors, and attorneys came about through necessity and practicality. This article examines this partnership and some of the conflicts and problems it contains. The article discusses the problems of overlap of authority between public health departments and elected officials. It also emphasizes that existing laws and regulations often provide sufficiently flexible authority, and that such laws and regulations can be exercised in new ways to address current public health problems. The article concludes with a discussion of the challenges faced by public health officials and legislators in forming a partnership to secure necessary financial support and legal authority for public health activities.

As the story goes, some healthcare providers were sitting on the bank of a river having lunch, their practice every day. They hear a person calling for help from the river, and he appears battered and bruised. Of course, they dive in, pull the person out, provide some first aid, and take him all the way up the long hill to the hospital. They feel good that they have helped someone that day. The next day, they go down to the river again for lunch, and now there are two people floating down the river, also battered and bruised. Again, they jump in the water, pull these two people out, give them first aid, and take them up the hill. The next day, the healthcare providers encounter four more battered and bruised people in the water, and the day after that they encounter eight, and so it continues. At some point, these healthcare providers said, "This is hard work, rescuing people and taking them up the hill every day, and we are not getting our lunch."

After some thinking, they take an old hearse and convert it so they can put people in it and then drive them up the hill. It saves time and money, and they get to eat lunch. Over time, they acquired an ambulance for $40,000. Of course, one ambulance is not enough if you have 40–50 people floating down the river every day, so before they know it, they have a fleet of ambulances–some parked at the river, some parked at the hospital-and they are pulling people out of the river, taking them up the hill, and providing them with comprehensive care. They really feel as though they are accomplishing something.

Still, the healthcare providers don't really get to eat their lunch in a leisurely fashion after all that work. So they decide to train special emergency medical technicians at about $5,000 each. Then, of course, they need at least two of them–a driver and someone in the back. They soon discover that the patients are complex cases and they need two EMTs in the back. So there are three EMTs at $15,000 for each ambulance. Still, it is all well and good, because lives are being saved and the healthcare providers feel good about that.

At some point, that burden that the health care providers felt at the bottom of the hill becomes a burden at the top of the hill. The providers go to the hospital and recognize that a much more

efficient way to provide the necessary care would be to take all of those very critically ill patients and put them in a special trauma unit, which, of course, has to be staffed. The needs of the unit include respirators, nurses, IV's and poles, special medications and boxes, and certainly a separate place for them to have lunch.

It costs about $300,000 a year to craft this very complex special trauma center with this special staff and its bells and whistles and high level medical technology, but the health care providers are not done yet. And at some point, they decide to buy a boat to improve the pre-hospital care response—one with a deck where people pulled out of the river can lie and be resuscitated. The boat can take the patients and the providers to the shore, where they can be placed in an ambulance that will take them up the hill for placement in that special care unit that saves so many lives. These boats cost somewhere around $850,000 a year, adding yet more to the budget. And then there is always that special place in the river—the place with the rapids—that even the divers can't get to, and certainly not the boat. And if that $850,000 boat were to be destroyed while the providers attempted to get up the rapids, the legislators would not be happy.

The next step, then, is to go buy a helicopter crewed by a special staff that earns flight pay, so the providers spend a little bit more money. A helicopter that has special equipment to take care of someone right on the river can go anywhere from $972,000 to $1.3 million. Still, lives are being saved more than ever. A wonderful system has been established. There are boats, helicopters, ambulances with special staff, and trauma units. The rate of patients being saved from the river is about 90 percent. Just the same, about 10 percent are lost or disabled during rescue attempts, an unacceptable rate that causes the healthcare providers to spend even more money to perfect the system. Finally, all those health care providers can sit back and marvel at the incredible system. In fact, it is the best care system that money can buy. Then, during rounds one day, some smart aleck—usually a medical student, occasionally a student rotating off discipline, an attorney or legislator who happens to be there for the day—asks that inevitable question: "Who's throwing all these people in the river?"

So these health care providers finally go up the river and look, and what they see is that there is a bar up on this cliff and a curved road at the bottom with a broken guardrail. When people drink and drive and zip around that curve, they hit the side of the road and drive into the river. Being clever health care providers, they pick up the phone and call the chair of the legislative committee, saying, "We have too many people in our community that are dying needlessly, and something needs to be done!" Then through plotting and planning with the legislative leadership, the providers succeed in getting a bill passed to straighten out that road and fund a better guardrail.

Later, the legislators get together with their attorney general and legal staff to change the laws that govern the behaviors that create the problem in the first place. The public health care providers get together with their staff to work in a very aggressive manner to change public behavior so that people don't drink and drive, don't speed on that road, and don't remain ignorant of the critical danger resulting from such behavior. Eventually, the trauma center is closed, and those incredible resources are moved to address such critical problems as reducing infant mortality or reducing childhood injury, or addressing the disparities in health care across the nation.

This story reflects a partnership, a partnership very much like the long-standing partnership developed by the founding fathers and mothers of our country—a partnership between public health, the legislative leadership, and legal supporters. It is a partnership that continues to grow, is dynamic in its nature, and is unstoppable. It is not a radical notion. Rather, it is a grass-roots effort, one that cannot fail.

Partnerships in New York

In New York City, the Board of Health has a great degree of legislative authority. That empowerment creates some real challenges,

because there are many mutual misunderstandings as to who does what. There is no fine line to define what public health is and is not. Events that many years ago seemed to be unrelated to public health—violence or homicides or domestic violence—are today recognized as clearly reflecting public health issues. The line has to be drawn clearly for many groups, including the Health Department, the Board of Health, legislators, chairs of the health committees, and the counsel for the legislatures. At present, there is a great deal of overlap of authority.

A few examples in New York City are illustrative of the problem. The City Council enacts all the codes—the building codes, the fire codes, the housing maintenance codes—except the health code, which is the province of the Board of Health. And yet, the City Council enacted a local law in the housing maintenance code, defining what lead-based paint is and establishing a maximum tolerance of .7 milligrams per centimeter squared. That standard was actually in the health code before the City Council enacted it. But then, the Board of Health learned that X-ray fluorometers were not quite accurate at below one milligram per centimeter squared. Following the science, the Board of Health changed that standard to a looser standard of 1.0, thereby creating a conflict between the two authorities. For a number of years the City Council found it difficult to go from an apparently stricter standard to a looser standard, and it therefore created a disconnect between the housing maintenance code and the health code remained— which created confusion in the courts and programmatic difficulties. Finally, the City Council amended the housing maintenance code.

Another indispensable partnership is the one between public health lawyers and public health practitioners. For some reason, public health emergencies always seem to happen on a Friday afternoon, at which time need arises for legal advice to be rendered to the health practitioner. The need for coordination between a legal adviser and a public health practitioner can be something as simple as securing a commissioner's order to permit going into a facility to access a patient database in the course of an epidemiologic investigation.

A more dramatic example of this need for coordination happened on September 12, 2001. The Public Health Department was located about 10 blocks from the World Trade Center, and on September 11, the phone systems and computers were all knocked out by the terrorist event. By September 12th, the Department had relocated to the Bureau of Laboratories, about a mile away, and the computers were all transferred there. Because public health practitioners were worried that there might be a bioterrorist incident, they sent out epidemiologists to various emergency rooms for surveillance. Some hospitals said, "What gives you the right to look at emergency room medical records? They're not reportable." The lawyers were called in. Although the books were not available, the Health Department's General Counsel knew that the health code had a provision in it, Section 11.03(b), that an outbreak or suspected outbreak of any disease or condition is reportable to the Health Department. That information was relayed to the practitioner in the field, who relayed it to the emergency room personnel and their lawyers, thus facilitating access to database information.

Although some public health laws are old, and in many cases need to be updated, existing laws and regulations often offer sufficiently flexible authority to permit their exercise in new ways. Public health laws are old, and in many cases they need to be updated. For example, consider syndromic surveillance—a system of accessing health-related information from non-traditional sources—whether the source be 9/11 data, emergency room data, employee sick calls, or school absences due to sickness. Information gathered through syndromic surveillance may make it possible to identify a situation well in advance of the time that information is supposed to be reported to the health officer in normal disease reporting situations. As some legal authority for this kind of surveillance one can look to a provision in the New York sanitary code which

states, "The city, county, or district health officer shall exercise due diligence in ascertaining the existence of such outbreaks or unusual prevalence of diseases." Just as in the case of the Constitution, clearly, the framers of that sanitary code could not have envisioned how it would be used in today's society. But if the old words fit the new circumstances, or the other way around, then public health practitioners should assume that the intent of the framers was to provide the health officer with the authority necessary to protect the public, and not hesitate to use this authority.

It is not necessary to start over by discarding all existing public health laws or to limit necessary public health interventions because of overlapping jurisdictions. Existing laws carry authority that has not been clearly examined by a knowledgeable body of public health lawyers and in many, but not all, instances can provide adequate flexibility in today's world.

Legislative Partnership

It is important to consider the partnership between public health and the law from a legislator's viewpoint, especially the viewpoint of a legislator involved in healthcare issues. One urge or desire that brings such individuals to the legislature is to ensure that people are healthy and well, and that the community can achieve the kinds of things that it sets out to achieve. Those legislators who are involved in promoting and advocating good public health policy run up against legislators who do not understand what public health is, and who believe that public health is simply making sure our air and water quality is better and that county health departments give immunizations. Some legislators believe that public health is simply assuring that a county Health Department can do a Pap smear or a mammogram, or offer some preventive kinds of tests. Some do not really understand the true mission or goal of public health.

The events of 9/11, however, created a different kind of dialogue with regard to public health and the role of public health officials. Discussion emerged regarding the ways in which public health interacts with and plays in with the law, and regarding who is responsible for what activities. The next fairly large and looming task ahead is to ensure that legislators across the country really do understand the changing mission and goals of public health. Nothing in public health remains constant. Public health is entirely different now from what it was 100 years ago, and will also be different from the present status 100 years from now. Legislators and other public policymakers need to identify the means necessary to accomplish what is needed now.

Public health experts often know what works and what needs to be done, but find it difficult to implement those things. These experts need supporting data to convince legislators to pass laws and provide the necessary financial support for sound public health decisions. It is an ongoing process to make sure that legislators across the country understand this notion of public health and the value of public health.

A partnership is needed to make public health a higher priority among legislators. A shared objective has to be established among legislators, public health officials, lawyers, and community organizations. There has to be some shared action, meaning there has to be a clear delineation of roles and responsibilities. Those roles and responsibilities, however, are not fixed. They are flexible. They must be flexible to address appropriately the kinds of things that make for a better, healthier public.

So how is the public kept healthy? Obviously, a child who is afforded early and adequate health care services will do better in school, and an adult who is provided early and adequate health care services will be more productive at work. These are proven results, and these are issues of public health.

Necessary partnerships, then, are not just with lawyers and not just with public health officials, but also with education officials and with labor officials. Once a healthier public is created, legislators are more willing to place the financial resources and other kinds of resources needed to move public health system a little further. Elected officials must see the connection

between both public health and being elected. Elected officials must understand that public health officials are not out there to usurp their authority and their control. Rather, they have to see that it is a partnership. The opportunity is here now to establish that continual dialogue, that communication that starts and continues as new public health policy is developed.

Public health must be made a priority, but there is a balance that has to be achieved between creating a healthier public and making sure that people's rights—individual rights—are protected. It is a hard balance for legislators. Issues such as seat belts, motorcycle helmets, and smoking exemplify the difficulty of achieving that balance of things that we know to protect public health.

If these things are known about public health, then why has the answer not been so apparent? Why have these things not come to be? Because, unfortunately, or maybe fortunately in this society, there are other forces beyond just those who believe in public health and beyond those who know the value of public health. There are other forces that come to play on the legislative arena. So, as the partnership is strategized and developed to improve the public's health, it is important to realize that there are those outside this process that bring pressure to bear on the legislature.

The challenge is before the legislature and those who work with legislatures to make sure that the voices of those who know public health are heard loudly and that public health officials have the documentation, the information, and the research that is necessary to make sure that the case is heard. And public policymakers must understand that this case is the right case. If the partnership is made to work effectively, not only will there be a clear idea and understanding of what public health is and the goals and the mission of public health, but there will also be a healthier public and a healthier population.

How Do We Translate Science into Public Health Policy and Law?

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ABSTRACT

Scientific knowledge concerning effective preventive measures to preserve and protect the health of the public continues to grow exponentially. Methods for assessing the impact of population-based interventions such as policies and laws have also greatly increased in the past decade, including systematic approaches that allow general findings to be drawn from various studies, especially those developed as part of the Guide to Community Preventive Services (Community Guide). However, the translation of the collected scientific evidence gathered to date has been spotty and problematic. Success stories do exist, including community water fluoridation, a significant factor in improvements in reduction of tooth decay over the past 50 years. Even for interventions with a strong science base, such as community water fluoridation, significant barriers to implementation of effective strategies discovered through research remain. Barriers include public misunderstanding of health issues and proposed solutions such as fluoridation; lack of engagement on the part of the media in communicating known effective strategies; and reluctance on the part of policymakers to champion approaches that concern but may not be advocated by their constituencies. The increasing burden of chronic disease places public policymakers into non-traditional roles, such as advocating behavior change as a preventive measure. Science is a critical tool to help legislators and policymakers "connect the dots" between public policies. For example, the elimination or degrading of physical education programs in schools is an important factor in addressing the national epidemic of childhood overweight and obesity in addition to the increase in rates of Type II diabetes among children. This article provides an overview of the past, present, and future associated with translating science into public health policy and law, including a review of tools and strategies to address existing and expanding public health challenges. The article also provides and discusses examples of translating and implementing science-based solutions to address public health problems effectively.

In 1753, James Lind, a British Naval surgeon, published the results of his studies on the efficacy of fresh lemons and oranges in curing scurvy. Despite the promising results reported, it was another 42 years until the British Admiralty formally recognized Dr. Lind's recommendations as the best preventive measure against scurvy and required a daily ration of citrus for all shipboard sailors.[1] When Goethe wrote, "Knowing is not enough; we must apply. Willing is not enough; we must do," he could have been talking about the challenge of applying what we know about science to public health law and policy. While the breadth of our understanding and knowledge about the causes of and preventive measures against disease, illness, and injury continues to

grow, translation of this body of evidence has been slow. When action is required in the legislative arena, it is driven by argument rather than science, further complicating the situation. This point is well illustrated by an 1893 Supreme Court decision, *Nix v. Hedden*. At that time, the State of New York imposed a 10% tariff on vegetables and imposed no duty on fruit. Mr. Nix, a fruit importer, opposed the state's imposition of a tax against tomatoes, because he considered them to be fruit. To botanists, the tomato always has been and ever will be a fruit. However, the court relied not on science but on the "common language of the people" and dictionary definitions of fruits and vegetables that held that vegetables were served "as a principal part of the repast, and not, like fruits generally, as dessert."[2]

In contrast, a few examples exist to illustrate the successful translation of scientific findings into public health policy to achieve extraordinary results. Examples include actions against tobacco use, prevention and limitation of transmission of infectious disease, and improved motor vehicle safety.[3] The stories behind these achievements demonstrate the interdependence of science with the social and political dimensions of public health.[4] Sound science is not always enough to change policy or create legislative action. To do so requires understanding of the role science has played and the way it can be utilized to influence public health policy and laws. It also requires an understanding of the roles of policymakers and legislators in addressing underlying public health issues such as unhealthy behaviors. The Public Health Law Program sponsored by the Centers for Disease Control and Prevention may play a role in attempting to document the linkages and relationships between science and policy and to build upon them.

To understand the place of science in the evaluative calculus of legislative and policy development as it relates to public health, one must review its historical progression, current application, and future opportunities.

Laws and Policies As Public Health Measures—History that Bears Repeating

Using science to inform public action to improve public health has been the critical foundation to what is now the statutory base for public health. Some of the most important laws were those that provided for systematic collection of data on human health and mortality. The Boston Board of Health, established in 1799, in 1810 passed an act that required recording the name, age, and disease of every person buried.[5] Lemuel Shattuck's prescient Report of the Sanitary Commission of Massachusetts in 1850 strongly advocated routine collection of demographic data and the need for regulation of environmental sanitation, as well as food and drugs.[6]

Cities and states led the way with public health legislation, and the benefits of legislation at these levels gave weight to the recommendations of the Committee of One Hundred on National Health (1906–1912).[7] This influential group, which advocated a strengthened public health service to help conserve "national vitality," was partially responsible for the 1912 Federal action expanding the responsibilities of the Public Health Service.[8] The over 30 years' increase in longevity during the 20th century reflected an almost unthinkable improvement in the health of the human species,[3] in large part due to improvements in pure water, pure foods, better nutrition, sewage/septic systems, and systems of public health surveillance and immunizations. In each case, laws made the greatest difference.

Other important laws also weighed public health benefit against individual choice, such as those that regulated driving conventions and speed limits, and the Highway Safety Act (1966), which systematically approached the problem of motor vehicle-related injury.[9]

Governments at all levels passed laws to protect health through regulation of various aspects of the free market. For example, the Pure Food and Drug Act (1906) regulated conditions under which food was produced,[10] while chlorination and treatment of drinking water

was first implemented in 1908 in New Jersey.[11] The Safe Drinking Water Act of 1974 regulated biological contaminants capable of causing infectious diseases.

Advances in the detection, treatment, and prevention of communicable disease decreased mortality, while chronic disease and occupational injury and illness emerged as major health concerns. The Federal Coal Mine Health and Safety Act (1969) and the Occupational Safety and Health Act (1970) are examples of industry-specific and comprehensive approaches to providing health and safety standards for workers.

These Acts did not come about based on the power of scientific discovery alone; they also came about as a result of the marriage of an increasing knowledge base, the political will to support change (and provide resources), and a social strategy to accomplish change.[12] Each of these factors is independent, as noted in Richmond and Kotelchuck's health policy model, but each is also interdependent.[13] No single component can produce effective preventive action, but each component must be present in some form to produce effective public policy and law.[4] Among the most illustrative examples of the current interplay between science and political will are continuing efforts to introduce community water fluoridation. While 43 of the 50 largest cities in the United States have fluoridated water, approximately one-third of the country's population does not have access to fluoridated community water systems.[14] Despite the overwhelming scientific evidence of its effectiveness, community water fluoridation continues to present challenges to political decision makers working for its introduction.

Water Fluoridation-Remarkable Success, Missed Opportunities

Dental caries is among the most prevalent childhood diseases.[15] Fifty percent of first grade children suffer from dental caries, while an astonishing eighty percent of 17-year-old children have some kind of dental disease.[15] In the United States, children miss more than 51 million school hours each year to dental-related illness.[15] The most shocking dynamic is that this condition persists even though the method to prevent caries is well known.

The dental profession has the tools to strengthen teeth, eliminate bacteria, encourage a change of diet, and repair defects through clinical interactions. Despite these tools and coverage of dental visits for children through state Medicaid programs, progress in treating and preventing dental disease has been limited, especially among low income children and among some racial and ethnic minorities. Poor children suffer twice as many dental caries as their more affluent peers, and their disease is more likely to be untreated.[15] Among school-aged children, about 80% of tooth decay in the permanent teeth is found in 25% of the children, mostly lower-income Mexican-American and African-American children.[16–17] Legislative action to support fluoridation of community water systems would appear to be a relatively easy solution to the epidemic of dental caries. Fluoride is naturally present in all water, and there is a history of proven efficacy and safety.[15] Community water fluoridation consists of the addition of fluoride to adjust the natural fluoride concentration of a community's water supply to the level recommended for optimal dental health.[14] There exists a long history of proven efficacy and safety of fluoridation, which is an especially important tool for those at greater risk for tooth decay, as its benefits extend to all in the population, regardless of age, racial group, socioeconomic status, or insurance coverage.[15]

In spite of the substantive medical and scientific evidence demonstrating the benefits of fluoridation of public water systems, the debate continues about fluoridation, and it is often a hotly contested and bitterly fought battle within legislatures. The consequences of current oral health policies that do not take full advantage of scientific knowledge and tools are a frightened and tentative populace, millions of children without the benefits of fluoride, and costly remediation of dental disease.

The key to the implementation of water fluoridation in public systems is the education of

the public as well as legislators. Part of this education comes from the media, who, regardless of their understanding of the issue, still possess the ability to influence the public. Public perception can then be brought to bear on governments to enact legislative or policy changes. Whatever the channel of communication, the following elements are necessary to create the legislative will to establish a public policy that will effectively control dental disease:

1. Public awareness of the extent of dental disease;
2. Knowledge of the correlation between dental health and overall health;
3. Informed legislative bodies;
4. Willingness to accept scientific evidence vs. fear-producing arguments; and
5. Commonsense leadership.

The Increasing Specter of Chronic Disease—When a Health Issue Necessitates a Policy Approach

Legislative successes in many states and communities also have done much to provide support for the role government can play in the control of disease and the promotion of public health such as is demonstrated by community water fluoridation. Recently, changing behaviors to prevent the transmission of infections has become an expected task for public health agencies. Even this role is controversial when the behaviors to be controlled are themselves controversial, as sexual behavior often is, or when the risks are seen as trivial, as with immunization against some childhood diseases. An even thornier question is whether chronic disease prevention is a legitimate role of government. Is preventing unhealthy behavior an appropriate subject for public policy and government action? Almost all public health officers would argue that it is, but doubts remain among many members of the public and many legislators.

If, as has been suggested by state legislators during this conference, prudent stewardship of public funds is important politically, the issue of chronic disease prevention as a responsibility of government is the $910 billion question. This figure represents 70% of the approximately $1.3 trillion annual direct cost in the United States related to the prevalence and cost of chronic disease. These costs can only go up in both crude terms and as a proportion of total health care costs as the population ages in the coming decades.[18]

Chronic diseases and conditions, which disproportionately affect women and racial and ethnic minorities, are often viewed as the consequence of poor behavior choices.[14] How much should we then invest in changing behaviors to prevent chronic diseases or to reduce the impact of unhealthy behaviors? When does government overreach and curb individual freedom and personal choice, keeping in mind that currently the public as a whole bears about half the total health care costs provided by the government through policies and programs such as Medicare and Medicaid? Given the financial burden borne by the government in the payment for health care related to chronic conditions, isn't it in the public interest to support legislation and policies that seek to foster personal health behaviors that lead to improved health and diminished health care costs? Although these behaviors are personal choices, government has readily recognized its role in fostering desired behaviors through such legislative strategies as speed limits and seat belt laws as health-related behaviors as well as tax benefits for home ownership and saving for higher education as non-health behaviors.

Science should be a tool for defining public policy for promoting behavior change to prevent disease. Science is a particularly important policy tool when we consider chronic disease prevention and health promotion, where the effects of behaviors and environmental exposures may be remote, complex, and interactive. Science can demonstrate the role of healthy behaviors in preventing and/or mitigating the effects of chronic disease, in addition to delineating the impact of unhealthy behaviors. It is important, however, to determine which behaviors really influence the outcomes we are seeking.

Science can guide public investment in strategies of behavior change that are more likely to work. We can identify the behavior changes that influence outcomes favorably. We can evaluate strategies that are intended to change those behaviors in the desired direction. These actions allow wise use of public resources to prevent chronic diseases and conditions.

Politics determines what policies will be adopted and what programs will be funded, including those that might influence behavior change and environmental exposures. The political process also influences the information and education available to encourage healthy behaviors and reduce unhealthy ones. Science generates and tests theories about causal relationships among healthy behaviors, behavior changes, and good health. The political process selects the applications in which this knowledge is applied to people. The challenge is to turn good science into a useful and effective tool for the political process.

Science That Connects Public Policies, Public Health Expenditures, and the Health of Citizens

Improved methods in four key areas have led and will continue to lead to public health advances in the prevention of chronic diseases and injury, as public health officials focus on major sources of premature death and disability. These areas are (1) population-based methods for health and risk assessment; (2) theory-based interventions; (3) assessment of the effectiveness of interventions; and (4) development of standards to compare intervention costs to net health benefits.[19]

An increasing need exists to organize and evaluate the wealth of scientific information available to help guide the formation of policy. The Community Preventive Services Task Force[20] and the Task Force on Community Preventive Services[21] are independent panels summarizing evidence and making related recommendations on a wide range of interventions. Both serve as evidence-based resources for decision makers and provide strong science that can be the best argument for implementing new policies and laws.

The Guide to Clinical Preventive Services (Clinical Guide), supported by the Agency for Healthcare Research and Quality, conducts comprehensive assessments of effectiveness of a wide range of preventive services, including screening tests, counseling, and immunizations that are delivered in a clinical setting. On the basis of the results of its review, the USPSTF makes recommendations about which services should be provided as part of primary health care. These recommendations, in turn, can provide a basis on which to make decisions about coverage/reimbursement and practice at both the public (e.g. Medicaid) and private (health plan) level.[22]

Beyond coverage of clinical preventive services, scientific evaluation has also been applied to preventive measures that (a) maximize the appropriate delivery of clinical services already covered, (b) promote health and safety in the workplace, and (c) promote prevention and well being among the general population. Because they are applied generally among the population, these measures, known as "population based" strategies, can help get healthcare issues beyond issues about access. They transcend individual status. Often, these types of interventions lead to legislative or policy actions that can be among the most successful public health measures. The Community Guide is relevant to this process.

The Community Guide (www.thecommunityguide.org), supported by the Centers for Disease Control and Prevention, systematically reviews a variety of topics with the objectives of developing a standard reference for effectiveness of information about population-based interventions and support of prevention research. This information can then be used as a tool for getting the most from community investments in prevention and health promotion. Current topics include risk behaviors (tobacco use, inadequate physical activity, prevention of HIV, STDs, and unintended pregnancy, alcohol abuse/misuse, other substance abuse, and poor nutrition); specific conditions (vaccine-preventable diseases, motor vehicle

injuries, diabetes, oral health, pregnancy outcomes, violence, cancer, and depression); and environmental and socio-cultural issues.[23]

The Community Guide uses seven steps in systematically reviewing the evidence and developing recommendations for a topic area: (1) convening a multidisciplinary development team; (2) developing a conceptual approach to organizing, grouping, selecting, and evaluating the interventions; (3) selecting interventions for evaluation; (4) searching for and retrieving evidence; (5) assessing the quality and summarizing the body of evidence of effectiveness; (6) translating the body of evidence of effectiveness into recommendations; (7) considering information on evidence other than effectiveness; and (8) identifying and summarizing research gaps.[24]

The Community Guide has already identified a range of community interventions of demonstrated effectiveness in addressing specific health issues. Examples include (1) school-based dental sealant delivery programs; (2) community-wide education campaigns to increase physical activity; (3) early childhood development programs; (4) mass media campaigns to reduce tobacco use; and (5) tobacco cessation telephone support systems. In each case, effective implementation requires policy decisions on resource allocation.

Examples of effective educational and behavior change interventions developed by the Community Guide include (1) distribution of and education programs about child safety seats; (2) school-based physical education; and (3) publicly funded, center-based comprehensive early childhood development programs for children 3-5 years old. Thus, population health can benefit from policies informed by evidence from the social sciences as well as the natural sciences.

Examples of effective policies to modify the physical environment as a means of improving population health include (1) creating or enhancing access to places for physical activity, combined with informational outreach; and (2) use of tenant-based rental assistance vouchers to improve household safety by giving qualified families a choice in moving to neighborhoods that offer reduced exposure to violence.

Both public and private policies have major impacts on health care outcomes. Healthcare system interventions demonstrated to be effective include (1) diabetes disease management and case management programs; (2) tobacco cessation provider reminders and provider education; (3) reduction of patients' out-of-pocket costs for vaccinations; (4) client and provider reminder systems for vaccinations; and (5) standing orders for vaccinations. Potential audiences for the Community Guide include public health departments, healthcare delivery systems, purchasers of health care, government (legislative and executive branches), foundations; community organizations, and academia.

Table 1 provides four examples of outcomes and community benefits of interventions examined by the Task Force on Community Preventive Services. These examples provide a framework for the development of policies and legislation on a sound science base.

Translating Science to Public Policy—Successful Program, Media, and Legislative Approaches

The following discussion provides examples of successful approaches to incorporating the findings of science into public health policy.

Promoting Physical Activity—A Program Approach

Government has an interest in the health of people. In a recent address, Georgia State Attorney General Thurbert Baker noted that our government is charged with providing for the general welfare of the people of this country (see General Baker's welcoming remarks in this issue). The government is a major payer for treating disease and disability, and therefore preserving health reduces government costs.

Science demonstrates that physical activity improves health.[25] Yet, we are surrounded by cues to be physically inactive. Many public policies, from the design of streets with sidewalks and

Table 1: Examples of outcome and community benefit of interventions examined by the Task Force on Community Preventive Services

Intervention	Outcome	Community Benefit
Increasing the Unit Price of Tobacco Products	Decrease tobacco use, helps promote quitting	Increased funding available for tobacco prevention and control can reduce state Medicaid costs for treatment of smoking related illness; reduced environmental tobacco smoke.
0.08% Blood Alcohol Concentration (BAC) laws	Reduces alcohol-related fatalities	Decreased risk of alcohol-related fatality. Passage by October 2004 prevents loss of federal highway construction funds
Community Water Fluoridation	Decreases tooth decay by 29% after introduction of fluoridation	Can reduce burden of tooth decay on productivity, especially among those without access to dental care
Enhanced School Physical Education Programs	Increases physical fitness among all kids	Decreases risk of childhood obesity while not hurting academic performance

neighborhoods to the marketing of cars to the organization of school curricula, currently support physical *inactivity*. It takes a major collective effort to change the cues to support increases in physical activity. We need to use science to inform the policy process with which government and community actions will effectively promote increases in physical activity.

Scientific studies collect the data to describe the levels of physical activity. The studies show current activity levels and trends and the consequences of various levels of physical activity on health. This information allows us to define physical inactivity as a health problem. When we have the science, we may need to use stories to convey the information. Scientific studies allow us to "connect the dots." We can show, for example, how highway design, planning and zoning ordinances, and school curriculum standards actually influence physical activity. When government actions are contributing to the level of physical inactivity, science is useful in developing collective action to change policies and programs.

The Community Guide, in its recommendations to increase physical activity, strongly recommends enhanced school-based physical education, the creation of and/or enhanced access to facilities for physical activity, and community-wide education programs. It also recommends point-of-decision prompts, such as reminders to take the stairs located near elevators.[26]

Of course, scientific studies to demonstrate the need for physical activity and systematic reviews of interventions to determine the most effective ones are not enough. It takes collective activity to change policies, develop and implement programs, and sustain interventions. Increasing physical activity at the community level takes collaboration. We must sustain partnerships over time.

An approach in Rhode Island is the development of measured walking paths in areas where people ordinarily walk, combined with supportive community and school projects around them. The concept was developed by the Irish Heart Association and is called the *Path to Health.*[27] Signs both to guide walkers and to tell them how far they have walked mark paths. Maps of the paths are provided in public places and on periodic signs on the paths. In Rhode Island, community groups, cities, and health care institutions have sponsored paths. Some are in state and local parks, and some are on city streets. Community groups help maintain the paths and develop walking clubs and related activities that use the paths. An evaluation of this effort is underway.

The combination of physical activity promotion with schools can be especially effective. *Healthy Schools! Healthy Kids!* programming combines the promotion of physical education, increased physical activity, and improved school environments.

Changing community design is also important. Health and environmental agencies can team up to promote walkable communities, greater use of parks and paths, and community designs that provide relationships among homes, businesses, and services within walking distance of each other. Smart Growth policies can be very

compatible with increasing opportunities for community-based interventions to increase physical activity levels.

Challenges and efforts to address physical activity levels are indicative of the multi-component strategies that states and localities will need to look to as the incidence and burden of chronic disease increases.

Improving Food Safety—A Media-Based Approach

An example of how the media influence public policy comes from Los Angeles. The Los Angeles County Department of Health Services implemented significant improvements in its restaurant inspection and grading system. The initiative came about as a result of a TV investigative report on hygiene levels in a number of well-known restaurants and the associated public and political outcry for improvement. The resulting evidence-based system incorporates grading (e.g., A, B, or C) with prominent posting, along with grading demerits based on the epidemiology of foodborne illness. The system changes resulted in (1) changed incentives—public behavior influenced by grades; (2) significant improvements in inspection scores; and (3) reduction in serious infractions and restaurant closures.[28] Additional evaluations revealed that restaurant grades affected profits, increased the incentive to improve food handling and storage procedures, and reduced reports of food borne illnesses

Addressing the Burden of Sexually Transmitted Diseases—A Legislative Approach

Enacting legislation can be one of the more difficult approaches to improving public health. The difficulties can be magnified when legislators do not fully understand the health issues or intervention, when the issue is emotionally or culturally sensitive, or when the proposed remedy involves mandated services by private insurers or other non-governmental health care organizations. Nevertheless, initiatives continue to be forged that successfully achieve public health progress through legislative action.

An example comes from the State of Georgia, where the state health department used a recommendation from a 1997 Institute of Medicine report on STD prevention in the United States for an insurance mandate to cover chlamydia screening for young women. The Division of Public Health, in partnership with several community organizations, mobilized a coalition of stakeholders to advocate for passage of the mandate during the 1998 state legislative session. The stakeholders, including women's groups, physician and nursing organizations, children's advocates, pharmaceutical representatives, and other health care leaders, supported the legislation within each group, reflecting the priorities and interests of their unique constituencies.[29]

Public health framed the discussions about chlamydia as an economic issue as well as a women's health issue. Instead of highlighting the potentially charged issues related to transmission of sexually transmitted diseases, public health emphasized the asymptomatic nature of chlamydial infection in women, the dangerous and potentially life-threatening sequelae, and the ease of treatment to prevent complications. Using Institute of Medicine projections, state public health officials estimated the current cost of treating chlamydia complications in women, estimated the cost to implement widespread screening, and noted the estimated cost savings if chlamydia screening were made available to all young women throughout the state.

Many legislators were not aware of the health risks of chlamydia or the potential long-term complications. The coalition's focus on education about the issue thus extended to the legislature as well. Maps with chlamydia rates by legislative district were a particularly effective tool to gain support from legislators previously unaware that this issue affected their district residents. The diverse support provided by the stakeholder groups resulted in bipartisan passage of the measure, one of the few insurance mandates ever to win approval by the Georgia legislature.

Several lessons were learned from the successful chlamydia screening initiative in

Georgia. To navigate the legislative process on any emotionally charged or sensitive issue, advocates should

1. Identify and utilize a group of diverse stakeholders and select a small, knowledgeable steering committee;
2. Educate legislative leaders and advocacy leaders;
3. Develop a plan to gain broad-based support and demonstrate the impact of the health issue by using legislative or regional maps;
4. Gather understandable and evidence-based facts (from a systematic review, if possible) and develop talking points; distribute fact sheets with clear, easy-to-understand information;
5. Activate a grass roots network;
6. Meet with editorial boards of the media;
7. Have a bill drafted and hearings set;
8. Work closely with the press at hearing time;
9. Produce a significant list of prominent local speakers to support the initiative;
10. Have state and/or national experts present concise statements of facts or support; and
11. Count votes and commitments before any legislative action is taken.

Conclusion

If saving money is important politically, it should also be acknowledged that in the face of health issues, doing nothing or the wrong thing can have serious financial implications for the government as well as for its citizenry. Making sound public policy decisions requires making the connections between spending of public health dollars, our public policies, and promoting the health of people. Scientific studies can establish the relationship between public policies and health outcomes. The synthesis of studies of community interventions to improve health outcomes provides vital information to use in making the connection between science and policy-making. The Community Guide recommendations on community interventions to increase physical activity have proved a very useful information source in guiding the implementation of programs and policies to increase physical activity levels in communities in Rhode Island, and it can very easily be applied in other states as well as localities.

Public health can use science and information to influence the public policy process. We need to present scientific evidence to support public policy change. Scientific evidence and solid data assist people and policy makers to understand the relationships among behaviors, our environment, and our health. Scientific evidence can also clarify the role that public policies and programs play in improving health, increasing healthy behaviors, and decreasing unhealthy ones. Using science to shape public health policy, especially in the area of behavior change, may seem a daring idea. However, to quote Goethe again, "Daring ideas are like chessmen moved forward; they may be beaten, but they may start a winning game." Good science *should* inform public health policy—including laws and regulations, funding decisions, and decisions that change incentives. We don't know all that we want to or should know about the causes of disease, illness, or injury, but we continue to learn more and are compiling ready-to-use assets for efforts at the state and local governmental levels to promote health. Initiatives such as CDC's Public Health Law Program and products such as the Guide to Community Preventive Services provide a rich set of resources for exploring how science can be translated into effective public policies.

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New Perspectives on Litigation and the Public's Health

Diana Bontá, Sandra Praeger, Jan Schlichtmann

ABSTRACT

This article provides redacted versions of three presentations by distinguished individuals with long experience in litigation or regulation to protect the public's health. A central theme is the need to develop partnerships to promote protection efforts. Jan Schlichtmann is internationally recognized for his representation of eight Massachusetts families engaged in legal action against two major companies, W. R. Grace and Beatrice Foods, in a fight to obtain justice in a groundbreaking case that has been the subject of many press and journal reports along with a nationally best-selling book and motion picture titled *A Civil Action*. His inspiring story of a long and difficult struggle to uncover the truth about contaminants in drinking water caused by buried wastes and to bring public health authorities and others together in a partnership to address the problem is a model of the use of litigation tools to protect the public's health. Diana Bontá, Director of the California Department of Health Services, discusses the efforts of her department to ensure the integrity of the Medi-Cal program that her department administers and the proper uses of litigation, including decisions to avoid litigation, for the purpose of protecting the public's health. She focuses on regulatory and legal efforts to protect her state's citizens and their environment, with an emphasis on the use of common sense in making decisions about whether to litigate and on partnering with advisory groups and members of the public as a means of aiding her department's accomplishment of its mission. Finally, Sandy Praeger, a state senator from Kansas, discusses efforts to use the law and regulation for the purpose of protecting the Kansas River. She stresses the importance of using sound judgment, backed by assessment of the legislative and physical environments, to make the right decisions regarding the use of the law for public health protection. She also points out that sometimes one can use the legislative process as an alternative to litigation to get a message out and force a correct decision.

Litigation is a valuable tool for the protection of the public's health. Three experiences represented here illustrate the uses of litigation and regulation, as well as the use of common sense in wielding these tools, in support of justice and the protection of the public's health.

Comments of Mr. Jan Schlichtmann

I like the title of this conference, *The Public's Health and the Law in the 21st Century, a Partnership Conference*. *Partnership*—it's a great word. It took me a long time to understand what it really means and to try to apply its meaning to my personal and professional life. My story is a story of a partnership.

As I looked at the newspaper and turned the television on today, I saw stories about problems caused by folks who think that there is profit in giving up your soul for the world. And I saw stories about terrorism caused by folks who think

it profits the soul to give up the world.

These two diseased visions of life, these kinds of soulless, unearthly visions, make us feel as though we're on the front lines of a war. At this point in time, it's hard to remember how the war began and nearly impossible to think about how it's going to end. The greatest task is just trying to figure out how you're going to survive today.

And I think we've figured out that we can't do it alone, not on our own. If we are to survive this way and achieve victory, we are going to need to come together at a time and a place like this conference and figure it out together—form a partnership.

I often hear people saying, "You know, hey, you're the lawyer and you've had this experience, and maybe you can dig around in that experience and maybe propose a law that would solve this problem or change administration policy or file a lawsuit. What's the lawsuit that could solve my problem?"

If I were asked that question at a younger stage in my career, I think I would have rattled off the law or the policy change or the basis of a lawsuit that would save us. But I've gone through an experience, and at the end of that experience, I began to think that maybe it's not just about laws and policy changes or lawsuits. These are tools, for sure, important tools in the toolbox. But like every carpenter, you don't blame your tools for bad work, and in the end it amounts to something else—something to guide our use of these tools.

When I started, I was very excited about being a lawyer. I loved and still love being a lawyer. In the earlier years, people came to me to help solve their problems. And I was a little more energetic and aggressive then. I liked protecting folks who were abused by the exercise of power, and I thought protecting them would be easy. They came to me while being threatened with destruction by power, and my response was, "No problem. I'll gather up all the power that the law gives me, and I'll try to destroy those who are trying to destroy my client."

But I went through an experience, and at the end of it I discovered the law of human physics: power destroying power is a physical impossibility. But in the early years, I didn't understand that. Now I do. I also learned something else—punished power always seeks its revenge. OK—no problem. If I can't destroy or punish power, then I would abuse power!

And I thought to myself, "Wait a minute. Me, abuse power?" And I became confused and lost, and a little afraid of it all, and I couldn't figure it out. If you couldn't destroy or punish or abuse, well then what role is there for me as a lawyer? And I figured there was no role, and so I went away. I went to Hawaii—not a bad place to go if you're going to have a midlife crisis. In that place, I tried to have a new life—no law and no past. And, of course, it didn't happen. But some other things had happened.

You see, when I took on the Woburn case, when the families came to me and told me about their problem—how they'd awakened to find their children sick and dying, and that their water, which these folks assumed was safe, was contaminated with common industrial chemicals they'd never heard of—they were filled with questions and wanted answers. And they did something else. They went around to neighbors, knocked on doors, and asked, "Do you have a child? Does your child have cancer?" And if the answer was yes, they went on down the list of addresses. And there weren't 6 children, or 12, or only 18. They found 24 cases of children with this disease, far too many in a small community over a short period of time.

And they went to the CDC, and they said, "We've counted the numbers of children with this disease, and there are too many. We want to know if the water is responsible." And they went to the EPA and said, "Our wells are contaminated, and we have a simple question: Who did it?" And the EPA and the CDC spent time and resources to go to the community of Woburn, one of the first times that these agencies had investigated a site. And finally they brought the families together. And the EPA said, "The wells are contaminated, but we can't tell you who and we can't tell you when." And the CDC said, "We've counted the numbers of children. There are too many, but we can't tell you if the water is responsible."

This wasn't satisfying for the families, and so they came together and made a decision, a bizarre

one. They said, "We'll get a lawyer." And they believed somehow that by getting a lawyer, they would get answers to their questions. And I remember sitting in my office and telling them, "Oh, no, no, no. You don't seem to understand. You see, I'm a lawyer. People come in with a problem, and I look at it. If I can make a case of it, well, I can help, and if I can't make a case of it, then I can't help. In order for me to make a case of this, why, there has to be a wrongdoer. Who did it?" And they responded, "The authorities don't know." And I'm thinking, "How much time and energy am I going to spend to find the wrongdoer and make a case of this?"

And I told the families, "The law requires something else—you know, a wrongdoer and a wrong. There has to be a connection, a thing called causation. Did any of your doctors tell you that your children's cancer was caused by contamination of the water?" And they replied, "Oh, no, no. The doctors don't know." And I'm thinking, "Is there a scientist or a doctor in this country, in this world, who'll make a witness in this case?"

You see, I didn't have the wisdom, the experience, or the resources to take on the case, and I told them so. But they wouldn't take no for an answer. And I did some research, as a lawyer does. I started looking at all the signs. And as I looked at the signs and did the research, they pointed to two corporations, two of the largest corporations in the world: W. R. Grace and Beatrice Foods.

And I began to think about things, and I heard the rumors—rumors about things buried on their property—valuable things, yes. And if you are quick enough and clever enough, you just might get on that property, you might be able to unbury those things, and people would pay huge sums to possess the information. And I sat there thinking. I thought about the children, about their needs, and about the challenge and the treasure. And I said, "This is what I want to do." And I went to my partners, and they said, "Hey, all for one and one for all." And we were on, and we joined the families on this journey.

And what a journey it was! It was a journey into science and into medicine, a journey into law and the legal system. And what I was to learn, as in all good journeys, is that this one had to be undertaken on a personal as well as a spiritual level.

You see, in order to bring a case that nobody had brought before, we had to talk to folks who had different experience and different knowledge. And we went to them. And one led to another and to another, and it became all very confusing. And so we decided to do something we'd never done before.

We brought a lot of people together at one time and one place. It was the first time that anyone had ever done it—no corporation, no governmental institution, no institution of higher learning had ever brought together all these folks from different experiences to ask a simple question: "Can these contaminates in a water supply make children sick, give them leukemia?"

There were a hydrogeologist, a geologist, an immunologist, a toxicologist, a cardiologist, a neurologist, a psychologist, and a psychiatrist. We're all in a room talking, and we had to come up with common language to answer the question. And they did answer it, and they came up with connections. We learned about the making of things. And when you make things, you also make waste. We learned about the chemical constituents of the waste. We learned what they did with the waste at the end of the day and where it went, and what happened to folks when it got there.

And we did bring the case that no one had ever brought before. The law gave us power, and we took that power and we got on their property. And on their property we discovered things—in pits. I learned a lot about pits. They're dug by people in order to bury things. Pits are dirty and dark and dangerous. And there was something else about pits. When you jump into somebody else's pit and you start digging, sometimes you end up digging your own. And something else about pits and burying things: No matter how deep you dig and try to bury things, those things have a very strange way of resurfacing.

And I found out something else. When you jump into someone else's pit and start digging, usually they return the favor and start jumping in *your* pits and start digging. And with all these invasions comes conflict, a war. And war was the

only way to express what it was. And it made for a good book, or a great book, and a good movie—not quite as good as the book.

But this was war, and we all know about war. Like every other war, this one went on too long. And like every other war, this one took everything. It didn't give back as much as it took. And it ended the way all wars do, the only way a war can end, in exhaustion. And it was the exhaustion of this experience that led me to another place hoping to forget the past and start a new one. But it didn't happen.

But something interesting did happen. You see, the EPA had looked at all the information that we shared and said, "You know, the families are right. These two companies are responsible." And they did something unusual. They invited the companies to a place and shared with them the information that we had shared with the EPA. And after all that sharing, something interesting happened. The two companies wrote a check for $70 million for a cleanup—it will take 50 years.

I heard about all this. And I decided to make that long hike home, from the lava rock of Hawaii to the bedrock of New England. And when I got back to my place, I began to think about the past and to think not about just what I had lost, but what I had gained.

And something else interesting happened. In the summer of 1996, the CDC, which had now grown to include the Agency for Toxic Substances and Disease Registry (ASTDR), brought the families back together. And the CDC said, "You know, the families are right. We've looked at the data. The data show that children who were exposed in utero to these chemicals in the water had 14 times' greater risk of contracting the disease of leukemia than those who were not exposed." And it was the first time that this agency had ever found such a connection. I remember that night. I remember going home in the company of the families that night, and there were not as many families as when we first started on the journey together. And I remember feeling no pain—only joy.

You see, it had been 17 years since the wells had closed and 15 years since Ann Anderson's son Jimmy had died. But I realized that night that it was not too late for the truth. The truth was not something you had to invade and dig up and take from someone. The truth was all around us. And it comes to us when we share experience. When we share experience, soil is created in which life can take root.

And since that experience, I've had time to think about and apply those thoughts to other things. And I've gotten a lot of phone calls. There was a phone call I remember from a mother in Toms River, New Jersey. She said, "We've read this book, and I have to tell you, Mr. Schlichtmann, we've got these wells, and they're contaminated with solvents as in Woburn. And we've got a lot of children with cancer, and these two companies—two large companies." It's always two large companies. And she said, "We have a lot of questions and few answers, and I was wondering if you learned something and you wouldn't mind coming down and sharing with us what you learned." Well, I couldn't say no to her, and so I did go.

You see, we chatted for a while about what we had learned. And at the end of all that chatting, something interesting happened. They formed a group, calling themselves TEACH-Toxic Environments Affect Children's Health.

There were 69 families, all with children with cancer. And we formed a partnership—again, a very good word. It was a partnership between lawyer and client. Partners look out for each other's interests. They understand that everybody has limited resources, and they look at problem solving as something that you do together. And together, we went to the local government and formed a partnership; went to the CDC and the ATSDR and formed a partnership. And we concluded, "You know, this is working."

And I decided that we would take it one more step. We would knock on the doors of the companies, and we did. And who should answer the door but the lawyer who used to represent Beatrice Foods! We sat down and talked and shared information. And we formed another partnership, a limited partnership whose provisions were that for a limited period of time, there would be no lawsuits, all rights would be preserved, and we would share information—to the extent that lawyers

can share information. We decided to figure out the past and what, if anything, should be done about it.

And I'm proud to tell you that, just last December, after three years of this process, we made a public announcement of a resolution for those 69 families—a resolution that will give them the tools to dig out of the rubble of that experience.

And I've been able to go on from there to other places—Fort Lauderdale and Florida, and other places. And I began to understand that these human-made problems have human-made solutions. And we can solve these problems only if we do it together. Together, we will learn to live on and with this earth and have a life that is safer, healthier, and better.

Comments of Dr. Diana Bontá

The population of California is now over 33 million. The California Department of Health Services has 6,000 employees who are responsible not only for the public health program, but also for the Medicaid program, called Medi-Cal in California. The budget for the department is $30 billion, with a *B*. And right now, the state is looking at a $23 billion budget gap. Cuts for all the state departments are under consideration. That cut for the Department of Health Services at this time is $1.1 billion.

Within the department, we have quite a number of attorneys who assist us—70 under the Chief of Legal Counsel, Barbara Yanemora. These lawyers handle administrative hearings and provide the substantive expertise as they work with the deputy attorneys general on cases that ultimately go to the superior court or beyond.

In the last three years, the department has had 2,750 requests for administrative hearings. Nine administrative law judges, themselves attorneys, and ten hearing officers hear these cases. There are now 829 law cases currently in the department. About 412 of them are in the Medi-Cal area. The second highest area of litigation is licensing and certification. About a hundred of the legal cases are in administrative areas and personnel. Thankfully, fewer than 50 of the cases are in the area of public health.

Medi-Cal dominates our budget and our litigation. When I first started in the department—even before I had taken the oath of office—I was contacted by the governor. Could I do an interview the next day? I said sure. I asked what the particular media was. Television, I learned. What was it going to be? The response was *60 Minutes*, the CBS show. Who was the interviewer? The response was Mike Wallace. And what was the topic? Medi-Cal fraud. My thought was that I would probably be the director of record who lasted one day.

We had the interview, which lasted 45 minutes. It was exactly what you would anticipate, very stressful. The interview that was aired subsequently was only a few seconds long. Essentially my message was, "I don't like fraud, the governor doesn't like fraud, and I'll work damn hard to get rid of fraud." I promised Mike Wallace that he could come back to California a year from then and that he would see that we had made significant progress in the allegations before us. And the allegations were that we were losing $1 billion of Medi-Cal money per year as a result of fraud.

As you can imagine, I had to develop a strategy quickly, and that's where lawyers were very, very useful. They helped to develop the strategy; created and implemented software programs to edit for patterns of fraud; set up a legal framework for issuance of moratoriums on the provider enrollments; created a definition of pharmacies to prohibit the use of the title as a provider unless medications are actually dispensed from a pharmacy location; and drafted at least three legislative bills to create monitoring sanctions, provide for jail and fines for offenders, and establish authority for higher penalties when children are used in a crime as part of fraudulent claims. You see, children were being used and victimized in fraudulent claims by virtue of unnecessary filling of pinhole cavities by dentists. Some claimants were even paying teenagers for blood samples to aid in the falsification of blood specimens.

Three years later, I think that we are the national model of how to ensure the integrity of the Medi-Cal funds so that they are used for people in need.

Attorneys in the department are also challenged by legislation. We are currently analyzing 420 bills, with 716 department-related bills going through the legislature. The California legislature is in session every year, with breaks only between the months of October and December. Even during the breaks, legislators are usually hearing testimony through task forces and through committee hearings. Every legislative session seems to have bills related to nursing home reform and labor issues, along with statutory changes and reimbursement formulas and components of the Aging With Dignity initiative that require significant legal consultation.

When Governor Gray Davis wanted to increase the monetary fines for state citations, it was the legal staff who sat down with our licensing and certification staff, and our legislative staff, to craft the language of the bill, to meet with the stakeholders, including the nursing home industry, labor, consumer interest groups, and the respective attorneys.

On an ongoing basis, we oversee the licensure of nursing homes, hospitals, community clinics, and numerous public health areas such as tissue banks and radiological entities.

As we make regulatory changes to these numerous licensees, we go through a regulation process that's probably very similar to what many of the attendees of this conference experience in their own states. As in many jurisdictions, our rule-making process incorporates a public comment period requiring an opportunity for interested persons to weigh in on a proposed regulation. And these comments, whether they're presented orally or in a written fashion at a hearing, result in changes to the proposed regulation. Our process takes anywhere from a year to eighteen months to get through a hearing. One regulation that is the final stages of issuance is the nurse-to-patient ratios for hospitals. Within 18 months of adoption of the regulation, we will have one nurse to every five medical-surgical patients as a ratio.

We certainly have been in the spotlight, with a lot of media attention. I expect that as we implement the regulation, we're going to receive requests from labor for reports of compliance, and we'll have the first challenge of citing non-compliant facilities.

How do we avoid litigation? First, there is a definite role for our advisory committees. We have 57 statutorily created advisory boards in the Department of Health Services. And though it takes a lot of time from our staff members and me to engage them fully, I think that they have some good remedies for us. They certainly offer an opportunity for us to discuss, in a public setting, the ideas and concepts that later become regulations. Examples of such advisory groups are our Lyme Disease Advisory Committee, our Advisory Committee on Human Cloning, and the Magnetic Fields Program Stakeholders Advisory Consultant, a program created by order of the California Public Utilities Commission to oversee research into the possible health effects of electro-magnetic fields and to use the research results to produce reports and information on EMF-related issues.

Now we can't predict whether ultimately we are going to have litigation in the area of EMF regulation, but the Magnetic Fields Program Stakeholders Advisory Consultant provides an opportunity to have a very public discussion and to be able to have scientists in the external academic setting join us to look at the best policies. We also can have input from the public we serve. It is really a way to look at the partnership that we need to have in our communities. That advisory group helped choose the topics of research, reviewed the requests for proposals, advised on the peer reviewers to select the contractors, and helped to select an external science advisory panel to judge our department's EMF risk evaluation guidelines and the risk evaluation itself.

I will tell you that we had a somewhat embarrassing case of litigation after I came to the department. It is the case of La Raza v. Bontá. It involved the Healthy Children's Organizing Project, the national counsel of La Raza, the Southern Christian Leadership Conference of Greater Los Angeles, and quite a number of other groups. It is an example of an advocate community that the department had been working with, but it

also helped to push the department in the direction that we really needed to go.

The California statute provides that, before July 1, 1993, the department should have adopted regulations establishing a standard of care, so that each child is evaluated for risk of lead poisoning by health care providers during the child's periodic health assessment. And California statute also provides that by April 1, 1993, the department must ensure appropriate case management for every child identified with lead poisoning. Well, you can imagine that in 1999, when I joined the department, we had not met these requirements.

Within six months, some colleagues with those groups told me that we had waited too long and that they were going to file. The Healthy Children's Organizing Project and others filed a petition for a writ of mandate, ordering the department to promulgate the regulations within 60 days of issuance of the writ. And the court issued the writ of mandate, granting that portion of the petition, and DHS subsequently adopted the regulation and the screening.

We did that in record time. And I think that's because this litigation gave us the push to take the right steps. It gave me the ability, certainly, to go to our agency and to the governor's office and say, "You know, when our friends are pushing us like this, we really need to pay attention. We really need to make the changes." Litigation can be a very positive thing.

Other programs and initiatives that have been started, continued, or expanded as a result of cooperative efforts between the department and advocates include such examples as breast and cervical cancer prevention and treatment, cancer research, the indoor smoking ban, the five-a-day nutrition promotion, the birth defects registry, and infant botulism treatment.

Not all these required litigation to get consensus, although some did. For the most part, these programs and initiatives required no litigation.

In California, a state with tremendous natural resources, we will see litigation to protect our environment. And in some cases the public's health will be perceived as not being protected. We have a case right now that deals with decommissioned radioactive materials at a level as low as reasonably achievable, or what is called ALARA. It is proposed to allow that waste to be placed in facilities licensed to receive it. And this issue has certainly been controversial.

Nevertheless, the public's health will not be perceived as protected when children choke on candy that is neither regulated by the Consumer Protection Agency nor by the FDA product recall. And it will not be perceived as protected when we don't have immediate recommendations on anthrax, smallpox vaccination, and potassium iodide distribution.

Yet, all of these areas require thoughtful analysis and ultimate action. It may not make all parties confident that we have made the best decision, but I think ultimately our roles as regulators will entail our using common sense as never before—and that, and a good sense of humor, is our best commodity.

Comments of Ms. Sandra Praeger

The role and interplay of legislation, on the one hand, and litigation on the other in setting public health policy is a complex one. I've been in the legislature for twelve years, and I've seen us go in both directions. An example will explain.

Several years ago, we had concerns about the water quality in our Kansas River; a lot of the pollution came from surface runoff from farms. And the farm industry is one of the top industries in Kansas. It's not easy to bring farming issues to the legislative process. Many of the 125 House members are from rural parts of the state, and many of them represent the agriculture industry.

One of the ways we thought we could begin to develop some public opinion in support of improving the water quality was to promote greater recreational access to the river. After all, if we told people, "Here is a river that's a great natural resource," and then we said, "By the way, don't eat too many fish from the river because they are contaminated, and be sure to use alcohol wipes on your hands when you touch a sandbar," then perhaps people might be interested in cleaning up the water.

One of the problems in canoeing the river is the sand-dredging operations. The sand is apparently very pure, the kind the microchip industry loves. At the same time, sometimes cables used in the dredging operations pop to the surface. They can ruin a canoer's day. That's not a very good environment for canoeing.

We wanted to have at least a moratorium on new sand-dredging permits so that we could determine the best access points for canoeing and promote that recreational activity. We tried to get legislation to that effect passed. We fell short.

The Corps of Engineers has control over the river, and it could decide whether to grant sand-dredging permits. I called the Corps of Engineers in Kansas City to point out that its guardianship was defective in this respect.

One problem is that if you take too much sand out of the river, the river wants to replace it. It goes to the path of least resistance. Silt and dirt get into the river as the banks degrade. Instead of a river channel, then, you've got a wide, marshy area.

The colonel who headed the Corps wouldn't meet with me, but he did agree that on Monday morning at 10 he would be in his office, and I could telephone him. As a courtesy to him, I decided I would meet him at that time in person. When I showed up at his office a few minutes before 10, I apparently created a scurry of activity as engineers began coming in. I also had the president of Friends of the Caw, the Indian name for the Kansas River, with me.

We met, we talked about the issue, and we impressed upon the colonel and the engineers the importance of putting a moratorium on those permits until we could determine the location of the best recreational access.

Three weeks later, I received a telephone call from the colonel's office. He said to me, "We just wanted to let you know that we denied the permits." And it took me a minute to realize what he was saying. His office hadn't simply delayed granting additional permits; it had decided that in the best interests of the Kansas River, it would not grant any more permits.

We did use the bully pulpit of the legislative process to get our message out. Ultimately, we forced those in a position to make the right decision. There are all sorts of ways to get a message across. In Kansas, it would have been very difficult to generate legislative support.

We had in Kansas still another issue, the diminished water quality standards in Kansas. In 2001, our Secretary of Health and Environment fought to stop an eventually successful effort to lower those standards. I was very proud of him, and he has received some awards for his work. I feel fairly confident, however, that the EPA will step in to challenge the lowering of the standards.

I think, in all, that you have to assess both the legislative and the physical environments before deciding on a way to go. Getting the message out about the Kansas River did encourage those who were in positions of power to make the right decision.

Conclusion

Sometimes litigation is the only solution to a public health problem. If that is the situation, then it is best to seek out partners to help in the process. Those partners can take the form of clients, consumer groups, public health agencies, advisory groups, and other entities. At the same time, litigation should not be the first choice of action. Other solutions, including negotiation, legislation, regulation, and even using the bully pulpit, are often effective means of addressing a public health problem and persuading the sources of public health problems to do the right thing. Even then, forming partnerships can help to spread the message and secure an appropriate resolution.

When the Law Is Good Medicine

Christine O. Gregoire

Sherlock Holmes and Dr. Watson went on a camping trip. After a big dinner cooked over the open fire and a bottle of wine, they retired to their tent. At 1 a.m., Holmes nudged Watson awake.

"Watson, what do you see?" He asked.

"I see millions and millions of stars," Watson said.

Holmes replied, "And what does that tell you?"

Anxious to impress his friend, Watson thought for a moment and then said:

"Well, astrologically, I see Leo setting in the west. Astronomically, I see a nearly full moon that will be setting in the west with Virgo. Horologically, I would estimate the time to be about 1 a.m. Meteorologically, I'd say we are due for a splendid day tomorrow. And theologically, I'd say God is in the heavens in all his glory."

After a pause, he asked, "What do you see, Holmes?"

Holmes paused a moment and said: "Watson, you twit! Someone has stolen our tent!"

The story reminds us all how important it is to look at the big picture and not focus too much on all the details.

I usually give a talk to students at the University of Washington pharmacy and medical school each year, in part to demonstrate that all attorneys do not have horns and cloven hooves. I think a few remain suspicious, and I understand that. Even before they begin their professional lives, the fear and loathing of malpractice suits is firmly rooted in these young medical students.

But despite the reputation, most lawyers get into our profession because they want to right wrongs, fight for justice, and use the law to solve real problems for real people—just as most doctors and public health officials got into medicine to heal wounds, prevent and cure disease, and ease suffering. So it is long past time that these professions work as partners to advance a common cause of a healthier America. But it's not enough just to say we should work together.

I want to offer five lessons for improving cooperation between the health and legal communities. I learned them first-hand while working on such matters as tobacco litigation, school violence and, most recently, prescription drug pricing consumer protection cases. But I believe they can be used in many other situations to address many other public health issues.

Lesson One: Seek New Allies Who Can Help Achieve Success

The first lesson I've learned is simple: Always look for new allies who can help achieve success.

Most major problems have some easily identifiable "players"—groups whose interest is obvious. But if we look beyond the obvious, we might find allies we never imagined.

When Attorneys General around the country began studying the issue of school violence, it seemed obvious to us that we should turn to law enforcement, educators, kids, and parents. So that's whom we talked to.

The kids told us quite clearly that next to home life, peer-on-peer bullying—or "dissing" as they call it—is a top cause of violent outbursts.

So, what did we do about it?

In Washington, we formed a task force, chaired by a pediatrician, and asked for recommendations. The task force drafted a bill that our legislature passed as law. The law requires school districts to have anti-bullying policies.

But we knew that wouldn't be enough.

We needed to get the message across to each kid individually and to his/her parents. We needed kids to know that adults would take them

seriously if they complained.

But who would have the credibility with kids to achieve that?

We quickly realized that with required vaccinations and back-to-school and athletic checkups, most children see a pediatrician once a year. So, working with the Washington state medical association, we produced a brochure called *Bullying: It's Not OK*. Every pediatrician and family practice doctor in the state is urged to give it to parents and discuss it with kids.

I'll confess. When I started looking at ways to prevent the kinds of horror we saw at Columbine and at far too many other schools, I didn't immediately think that the folks who treat our kids for chicken pox and mumps would be such an important part of the solution. But they have been. Because I found bullying is a public health issue for our kids. So I've learned never to stop looking for new and unexpected allies.

Lesson Two: In Fighting a Powerful Enemy, Always Find Partners

The next lesson is that when stakes are high or the issues are complex, it is essential to find partners. When fighting an entrenched enemy—such as the tobacco industry-one needs to amass enough power to be a threat, not merely an annoyance.

The tobacco industry had controlled the legal arena for decades. Anyone even thinking of challenging tobacco could count on encountering a scorched-earth legal strategy aimed at dragging out the case and draining the resources from smaller opponents.

The state AGs learned power in numbers was essential in this case. It became very clear early on that if we allowed the tobacco companies to take us on one at a time, they could break us.

When Washington state went to court for the first hearing in our tobacco lawsuit, we had three attorneys on our side of the courtroom. On the other side were 17 tobacco attorneys, including some of the best—and most expensive—lawyers available in the country. But there was more to the picture than that.

In addition to Washington, there were more than 40 other states suing or threatening to sue tobacco companies. And we had new legal theories, including the ones used in Washington that the industry was violating our antitrust and consumer protection laws.

So it was this avalanche of lawsuits that brought the industry to the bargaining table. But once we got there, we had other help as well.

Because we didn't understand the solutions nearly as well as the public health community, we brought Matt Myers from Tobacco Free Kids and Dr. Lonnie Bristol from the American Medical Association to the negotiating table. And I consulted by confidential conference calls with public health officials from my home state on a regular basis during negotiations.

That combination of legal might and public health insight was essential to getting true reform in this industry. It demonstrated the power that people can exert when they work together, forgetting about who gets the glory or whose idea wins the day.

Lesson Three: Litigation Should Focus on Achieving Fundamental Change

The next lesson is to remember that lawsuits shouldn't be just about money, but about making fundamental change.

This may be an unusual concept for people in the medical profession, but the truth—strange as it may seem—is that litigation can be a friend.

The tobacco settlement is often described as the largest financial settlement in world history—$206 billion in the first 25 years, with payments to the states to go on in perpetuity.

But the money isn't what I am most proud of, and it wasn't what we worked hardest on or what the tobacco companies fought most strenuously. The most important part of the settlement was the injunctive relief. That's how we forced big tobacco to stop targeting our kids and to start telling the truth about tobacco.

And if anyone questions whether that injunctive relief had teeth, look at our case in California,

where we alleged that RJR violated the no-targeting-kids provision. Two weeks ago, the court fined RJR $20 million for that violation.

As attorneys, we obviously needed help from health officials to establish and pursue these goals. Going into the tobacco negotiations, public health experts told us most people could be prevented from becoming addicted if they were kept tobacco-free as kids. That guidance led us to decide that the best thing we could accomplish would be to establish new initiatives that would reduce the 3,000 kids who start smoking each day.

And we soon got a sure sign that the restrictions that the public health community suggested were on target, because the tobacco companies had a much easier time writing checks with lots of little zeros than they did accepting the new rules of corporate behavior.

They even told us that if they put enough money on the table, we couldn't walk away. They were wrong—because we understood the same thing they did: Money alone—no matter how huge the sums-wouldn't bring about the fundamental changes that could make a real difference.

Lesson Four: Dealing with Serious Health Issues Will Usually Turn Political

This brings me to my next lesson. Like it or not, dealing with serious health issues of a new century will usually turn political, and we have to be prepared to play in that arena.

Again, I look to my experience with the tobacco settlement. Getting the tobacco companies to agree was one thing. Getting more than 40 elected Attorneys General to agree was another. Then there were the media, Wall Street, state legislators, governors, the White House, tobacco farmers, Congress, smokers, public health officials, and more.

So while it's important to dream big, we also have to set realistic goals.

Public health groups were some of our greatest allies—and our greatest detractors as we pursued settlement. Often during the long course of tobacco negotiations, I had people tell me that I was losing the war or failing in my role as AG because I wasn't putting the "evil empire" out of business.

But these lawsuits weren't about putting a company that was manufacturing a legal product out of business. The lawsuits were about making companies abide by the law. And the public health professionals who helped make the settlement possible had the courage to be practical. They had the courage to get beyond rhetoric and understand that one can't walk away from a deal that is better than one ever dreamed just because it isn't absolutely perfect. They had the courage to recognize that victory doesn't always come when we expect it or look the way we wanted it to.

Lesson Five: Communication Is the Key to Public Health Improvement Efforts

The final lesson is that we need to communicate better.

We've got to learn to talk to the public by showing them the faces and stories behind the public health issues, not just by offering them a bunch of statistics.

And we've got to communicate with each other, talking about problems we see as they arise, not assuming that people in the medical community know about problems in the legal community and vice-versa.

And we've got to learn to talk to lawmakers about problems and solutions, because legislation can be every bit as important to public health as litigation or a prescription.

Even after winning the litigation in the tobacco settlement, it's still the state legislatures holding the purse strings. Public health groups have been united in trying to preserve the settlement funds for prevention programs and public health. But in far too many other states, we're losing those battles. Too many states, mine included, are relying on tobacco settlement money to balance their budgets rather than to promote public health issues. Why are we losing this battle?

Because other people, other causes speak louder and sometimes more eloquently to lawmakers. We need to understand that we can carry the debate if we talk about real people with real problems and point out that those dollars could mean the difference between life and death.

The sad truth is that a good story or a sympathetic face can too often trump solid facts and evidence. The pharmaceutical companies proved that in my state when they fought a bill that would save everyone an awful lot of money by developing a formulary consisting of the most inexpensive but effective drugs available.

Doctors liked it, groups representing the elderly and poor liked it, budget hawks liked it.

The pharmaceutical companies, on the other hand, hated it. But they couldn't provide any evidence that this was going to be a problem for anyone or anything but their bottom lines. They didn't have any facts to support them.

But with offers of free transportation and free lunches, they could bring busloads of people to the legislature. And that's just what they did.

They brought elderly and disabled people in to complain about the bill—people who didn't have any real idea of the nature of the bill. In fact, one of the people a drug company brought to testify against the bill later told a newspaper reporter that after listening to the testimony—for and against—he actually thought the legislation was a good idea.

But even though the facts weren't on the drug companies' side, those human faces helped kill the bill.

We've also got to communicate with each other. Let me give an example of what I mean.

Doctors, nurses, and public health officials in our communities know that too many patients are struggling to afford their prescription drugs. Doctors and nurses see too many of our elderly making a dreadful choice between food and medicine. So these doctors and nurses brought the problem to the attention of some public lawyers.

The medical profession saw suffering and impossible trade-offs. This is what we found: Some drug companies that reached price agreements to stifle competition, some that abused patent laws to keep less expensive generic drugs off the market, and some that illegally controlled supply.

So we've successfully filed suit against two drug companies and have cases against three others now pending. Just as the legal community would not inherently know or understand the access problem with prescription medicines, the health community cannot be expected to understand antitrust laws.

That's why we have to keep talking, especially about the problems that impact people's health and wellness. Public health and public law fight two of society's greatest enemies: illness and injustice. And when we combine our expertise and our resources, we can address both.

Or, as I tell the medical students I talk to each year, "Don't fear the lawyer." These students often think they can achieve success only by writing a prescription or by performing a surgery. That's a success for one patient at a time. But to succeed in improving the health of an entire population, we need to keep the tools of litigation and legislation ready along with the prescription pad and scalpels.

Lyndon Johnson once said, "There are no problems we cannot solve together, and very few we can solve by ourselves." If the public health and public law communities can remember those words, if we can continue to forge new partnerships and strengthen the ones we already have, we can improve the health of all Americans.

Do We Need a New Law or Regulation? The Public Health Decision Process

Georges Benjamin, Daniel J. O'Brien, Donne Trotter

ABSTRACT

New laws or regulations may not be a practical response to a public health threat. While in some instances legislation or regulation may be the only alternative to protecting the public's health, in many situations public health authorities and their legal counsel must consider alternative approaches to abating threats. This article provides an overview of the alternatives available to the public health official by providing discussion of a "legal tool box" available to public health officials. It also presents scenarios, with commentary, that serve as the basis for illustration of other means of intervention.

When faced with an emerging health threat to a community, public officials must determine what, if any, response is appropriate. Some problems are sufficiently novel or threatening to warrant new legislation. In most instances, however, existing legal authority will suffice. Often, more than one legally permissible way exists to exercise this authority. Before seeking new legislation to address the emergent threat, it is often useful for public health officials to consider not only the scope of current agency authority, but also the range of available options for exercising this authority.

Health officials successfully fulfill their core public health obligations by carefully balancing clinical, political, and legal considerations. It is not enough for a controversial public health measure to be scientifically correct. After all, political opposition or legal challenges may delay, impair, or even block the adoption of needed public health measures. By examining the scope and application of current law, health officials increase the probability that public health objectives will be satisfactorily met.

From a legal perspective, there are often multiple strategies that can be used to effectuate a public health objective. Legal advisors can better evaluate the relative effectiveness of these alternatives if they are involved in the decision-making process and understand the scientific and policy considerations at issue. Similarly, health officials can better address public health concerns when they understand the legal ramifications of their decisions.

When a threat to the public's health emerges, health department personnel must evaluate the problem from multiple perspectives. How serious is the threat and how quickly must it be addressed? What internal and external resources can be mobilized? What is the scientifically correct response, and will this response enjoy broad public support? As the following scenarios illustrate, this inquiry stands at the heart of the interface between the practice of public health law and medicine.

The "Legal Toolbox" For Public Health Officials

In most jurisdictions, it is no small feat to secure the passage of a new statute, regulation, or ordinance. The process is often time-consuming

and adversarial in nature. Proposed initiatives are routinely amended, and final bills may bear little resemblance to the sponsor's initial proposal. Given the obstacles to enacting new measures, public health officials must, on a day-to-day basis, find other means of achieving their public health objectives.

Fortunately, courts and legislative bodies have largely preserved the broad public health powers that emerged in the late 19th and early 20th centuries. These early "rules of engagement" allowed infection control officers to quarantine cholera patients, respond to pandemic influenza outbreaks, and eradicate smallpox. In many jurisdictions, today's health officer will rely on the same statutory authorities that guided predecessors a century ago. Although these core health statutes remain largely intact, the procedures governing their use have undergone unmistakable changes. Perhaps the most striking change is the emergence of due process protections that were largely ignored fifty years ago.

When confronted with a threat to the public health and in the absence of a clear legislative directive, what are a health officer's legal options? The public health "legal toolbox" furnishes more options than may be apparent at first glance. These options include

1. Adoption of Regulations—provided there is an adequate statutory basis allowing the adoption of broad-based regulatory standards.
2. Judicial Enforcement through a contested case involving identified parties, provided there exists clear regulatory or statutory authority to act.
3. "Cease and desist" nuisance orders. Relying on broad nuisance abatement powers, public health officials may order specific individuals to correct conditions threatening the public's health.
4. Declaratory decisions that direct specified parties to engage in behaviors that will preserve the public health and conform to existing legal requirements.
5. Health advisories, which provide general guidance and direction for preserving the public's health in areas where clear regulatory authority is lacking.
6. "Marketplace" regulation. By declining to take affirmative enforcement actions, health officers may choose to allow private citizens and interest groups to pursue legal enforcement of their own claims.

Illustrative Case Studies

The following two scenarios can serve as a basis for discussion of a range of options that a public health authority could elect as a means of addressing a threat:

Cosmetic contact lenses: Maryland

There is a growing market for cosmetic contact lenses, which are purchased by adolescents and young adults without a prescription through beautician shops and street vendors. A local television news program reported on this growing fashion trend. The reporter interviewed high school students who suffered serious eye injuries from wearing improperly fitted lenses. As part of this investigative report, a number of regulatory agencies, including the state health department, were asked what licensing and enforcement protocols were in place to safeguard unsuspecting buyers.

Needle exchange programs: Illinois Senate

Significant clinical evidence supports the proposition that needle exchange programs can help reduce the incidence of HIV transmission between intravenous drug abusers. In Illinois, supportive legislation introduced in the state senate repeatedly failed on grounds that such measures "sent the wrong message" and undermined efforts to deter illicit drug use. Despite successful efforts to secure bipartisan sponsors, it has been difficult to achieve consensus that the use of contaminated needles is a public health rather than a law enforcement issue.

Choosing the Right Public Health Legal Tool

In each of these scenarios, legislation could have been adopted to specifically address the

public health threat. Gaps in the regulation of cosmetic contact lenses prompted calls for a legislative solution. However, legislation has yet to be adopted to deal with this public health concern as well. Public health officials must nevertheless seek means of addressing a known threat, using existing legal authorities.

Responding to the emerging threat posed by cosmetic contact lenses involved educating potential consumers. The media highlighted the issue in the first instance and provided teenagers with graphic evidence of the dangers posed by even short-term use of improperly fitted contact lenses. Maryland health officials also developed a complaint and inspection protocol through which cease and desist orders were issued to a variety of retail outlets. This protocol may have provided less comprehensive protection than would emerge from a full-scale legislative initiative; however, prevention efforts stemming from the response chosen were effectively designed and implemented in a matter of days, rather than the months or years required for a legislated solution.

Sometimes new legislation really is needed to achieve public health goals. In these circumstances, the question becomes how best to secure support for the legislation. In Illinois, Senator Donne Trotter unsuccessfully offered legislation to expand needle exchange programs for nearly a decade. Despite broad support from the medical and public health community, the proposals never moved out of committee. In 2002, the General Assembly finally passed Senate Joint Resolution 58, which created an advisory commission to study the efficacy of needle exchange programs. This approach offers advocates and opponents of Senator Trotter's bills an opportunity to examine the scientific merits of the program. The goal is to build support for a new public health proposal aimed at reducing HIV transmission to intravenous drug users.

Taken together, the scenarios illustrate the need to consider a range of non-legislative responses to emerging public health threats. Legislative action may be necessary in some instances, but certainly not in all instances. Public health officials and their counsel are in the best position to evaluate alternative approaches through considering the full range of legally permissible intervention strategies.

Conclusion

Public health officials must be ready to use the full range of tools in the legal tool box to address public health threats. Legislation and even regulation are not always the answer. In addition, the months and years required to pass a legislative initiative, even in the unlikely event that opposition is minimal, may result in an inadequate and a delayed response to an urgent threat. Judicial enforcement, cease-and-desist orders, declaratory decisions, health advisories, and even marketplace regulation are options available for using the law as a means of protecting the public's health.

Building the Legal Foundation for an Effective Public Health System

Edward L. Baker, James S. Blumenstock, Jim Jensen, Ralph D. Morris, Anthony D. Moulton

ABSTRACT

Work has been underway nationally since the mid-1990s to equip state and community public health systems with the infrastructure needed to perform essential public health services. Key components of that infrastructure are a competent workforce, information and communication systems, health department and laboratory capacity, and legal authorities. As part of this transformative work, standards and assessment tools have been developed to measure the capacity and actual performance of public health systems. In addition, a number of states have examined the legal foundation for public health services and have revised and updated those authorities to improve their system's capacity in the context of evolving health challenges. Among those states are Nebraska, New Jersey, and Texas, all of which, beginning in 1999, have adopted dynamic new approaches to aligning public health's legal authorities with new missions and expectations for performance and accountability. This article describes the approaches that these three states have taken to strengthen their legal foundation for public health practice, to illuminate the perspectives legislators and health officials bring to the process, and to give decision makers in other states practical insight into the potential benefits of reviewing and restructuring public health's legal authorities. The underlying stimuli for the states' initiatives differed significantly, yet shared an important, common core. What they held in common was concern that outdated elements of the public health system and infrastructure hindered delivery of essential public health services at the community level. Where they differed was in the type of tools they found most suitable for the job of rejuvenating those structures. The approaches taken, and the policy tools selected, reflect the unique health needs of each state, establish relationships among state and community health authorities and agencies, and provide guidance by elected and appointed policy makers. Each state continues to refine its approach as it gains experience with the new authorities.

The initiatives of three states to update the legal foundation of public health practice and its infrastructure offer models that other states can adopt to prepare their public health agencies to cope with the needs of the 21st century. Each of these states—Nebraska, New Jersey, and Texas—has involved public health officials and legislators in the task of drafting and passing legislation that provides for funding of public health practices, modernization of legal authority of public health agencies, and revision of the public health infrastructure to ensure the provision of public health services to state residents.

Nebraska's Approach to Building a Legal Foundation for Public Health

Nebraska's approach to its issues is embodied in Legislative Bill (LB) 692 of 2001, sponsored by Senators Byars, Jensen, and colleagues. Concern with local public health services had been longstanding in Nebraska and was accentuated in areas of the state where public health services were virtually absent. Prior to 2000, there were 16 public health departments in the state, serving 22 of Nebraska's 93 counties and approximately 57% of the state's population.

The Nebraska Department of Health and Human Services, in conjunction with a Nebraska Community Health Partners Stakeholders Group and the Nebraska Partnership of Local Health Directors, with funding from a Robert Wood Johnson Foundation (RWJ) "Turning Point" grant, completed a state "Public Health Improvement Plan" and received additional RWJ funding for implementation of the plan. As of June 2001, four implementation projects had been funded, serving an additional 26 Nebraska counties and an additional 13% of the state's population.

Up to $10,000 was provided to each approved grantee and matched by local project organizers. Funded projects were required to include at least four counties, a formal organizational structure, a broad-based coalition, full time staff, a focus on a broad definition of health, development of a local public health improvement plan, and emphasis on coordination rather than direct provision of public health services.

LB 692 made significant changes in Nebraska law relating to the formation and function of local public health departments (LPHDs) and provided for the use of $50 million annually from trust funds containing tobacco settlement and Medicaid intergovernmental transfer revenues for health related purposes. Of that amount, LB 692 included an annual appropriation of $5.7 million for public health services, public health planning, and public health infrastructure development. Legislative intent emphasized statewide access to public health services and the establishment of local public health departments, required LPHDs to work collaboratively to assure the full range of public health services, and provided that LPHDs "should be able to" carry out core public health functions.

Of the $5.7 million annual appropriation, $100,000 was designated for additional public health personnel at the Nebraska Department of Health and Human Services and $5.6 million for county public health planning grants and aid to local public health departments as follows: (1) $465,000 for planning grants to counties ($5,000 per county), (2) $2 million in base funding for LPHDs, and (3) $3.1 million in per capita funding for LPHDs.

Local public health departments are eligible for base and per capita funding if formed by at least three contiguous counties with a total population of at least 30,000, or by one or more counties with a total population of at least 50,000. The legislation required LPHDs to provide core public health functions and submit annual reports to the state.

Annual base funding is distributed according to the total population served by the LPHD as follows: (1) $100,000 to LPHDs serving 30,000 to 50,000 persons in three or more contiguous counties, (2) $125,000 to LPHDs serving between 50,000 and 100,000 persons, and (3) $150,000 to LPHDs serving 100,000 persons or more.

The Nebraska Department of Health and Human Services reported that, as of May 31, 2002, at least fourteen new local public health departments have been formed, with two more expected in the near future. LB 692 also provided an annual appropriation of $2.8 million for minority health initiatives, with $2.6 million of that amount designated for targeted minority health initiatives in counties with at least 5% minority population. A total of $225,000 was designated annually for the establishment and operation of a satellite office of minority health in each of the state's three congressional districts.

The Nebraska Department of Health and Human Services expects to receive approximately $9.7 million in new federal terrorism funding, a

significant portion of which will be directed to local public health departments, and the Nebraska Emergency Management Agency expects to receive more than $30 million in additional federal funding for terrorism preparedness.

The Nebraska Legislature will continue to focus on further public health policy development, reauthorization of public health funding, and legislative oversight. A Nebraska version of the recently drafted Model State Emergency Health Powers Act was introduced in 2002 (LB 1224), and Nebraska is one of six states participating in a Robert Wood Johnson-funded model public health law collaborative. LB 692 (2001) also required the Health and Human Services Committee of the Legislature to direct an "evaluation and planning study" of publicly funded health and human services in the state, including public health. The committee is required to develop specific legislative proposals and issue a report of its activities and recommendations on or before January 1, 2003.

New Jersey's Approach to Building a Legal Foundation for Public Health

With 115 local health agencies and more than 500 local boards of health, New Jersey typifies the jurisdictional geography of public health in many states. Providing the full spectrum of public health services can strain the resources of small jurisdictions.

In 1997, the New Jersey public health community began a systematic process of assessing community-level public health organizations and resources. Convened by the state health department, the 31-member Public Health Task Force represented all sectors of the public health community. The process led to consensus about problems and opportunities and ultimately resulted in a comprehensive set of Public Health Practice Standards of Performance for Local Boards of Health. These standards—conceptually related to those developed by the National Public Health Performance Standards Program and its many partners—pertain to the infrastructure that undergirds and makes possible the provision of community-level public health services. The standards were pilot tested in Bergen and Morris counties as "countywide local governmental public health system models", published for public review and comment, and refined further before being issued as proposed regulations.

Key provisions of the proposed rules include

1. "Building public health infrastructure through workforce assessment, licensing and certification standards, training and development of workforce competencies, development of communication systems to collect and disseminate data, and the benchmarking and development of organizational capacity."
2. "Minimum standards for staffing and activities of local health agencies and…access to regional expertise…in a countywide or multicountywide area…"
3. "Evaluation of performance…based on outcomes and…to incrementally build local health agency infrastructure and capacity [and] a method to provide accountability to assure the performance of local health agencies."

Texas' Approach to Building a Legal Foundation for Public Health

The Texas approach is embodied in House Bill 1444, sponsored by representative Diane White Delisi and enacted in 1999. It combines both a significant reconceptualization of public health and practical restructuring of public health institutions.

HB 1444 responded to a study of local public health services conducted by the state Department of Health, the Lyndon Baines Johnson School of Public Affairs (at the University of Texas), the Blackland Research Center, and the School of Rural Public Health at the Texas A&M University. In HB 1444, Texas was one of the first states to formally register in statute the mission and functions of public health in terms of the Essential Public Health Services, a ten-point consensus statement adopted in 1994 by a consortium of national public health organizations (available at

<http://web.health.gov/phfunctions/public.htm>). In so doing, Texas adopted an undated perspective on communities' public health needs and also established an obligation for local health departments to address those needs.

New mechanisms were included in the legislation to strengthen the capacity of local health departments to address public health needs. Most importantly, the bill established a new program of state grants for provision of local public health services, with grant amounts determined on a per capital population basis. Local governments receiving these grants are required to develop plans to "evaluate the effectiveness, accessibility and quality of services…identify intended outcomes resulting from the use of the grant money and…establish performance standards for the delivery of the services…"

In areas of the state where no local government entity provides public health services, HB 1444 requires the state health department to provide those services and to develop a plan like the one required of local health departments. Further, the new legislation requires the director of a public health region—which typically contains multiple localities and local health boards—"to perform the duties of a health authority…in a region where there is no health authority…," effectively superceding the authority of local boards of health in such regions. The bill also created a public health consortium of health science facilities to provide technical assistance and applied research to the state and local health agencies.

HB 1444 was very important to local health departments in Texas. For the first time in Texas history, there was a legislative definition of public health in the context of the ten Essential Public Health Services. The services are important to defining the scope of programs when negotiating with a city or county for local funds to match state dollars. The definition of public health in HB 1444 was also used as a basis for determining what entities were eligible for the bioterrorism grants that were recently awarded to Texas.

Conclusion

Each of the three states employs a different approach to building a legal foundation for an effective public health system, but the three have in common a concentrated effort to reform the public health infrastructure and to update the legal foundation of public health practice as a means of addressing current needs. Moreover, all three approaches focus on key elements of a modern public health infrastructure. Through bringing the perspectives of health officials and legislators to bear on the problem of providing public health services to state residents, these states offer a model that other states can adopt as they examine their own public health needs.

Legal Preparedness for Bioterrorism

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ABSTRACT

Responding to a terrorist biological weapon attack poses new challenges not only for the public health response community but also to the very construct of public health police powers as we know them today. States are debating the merits of revising and updating these powers in order to ensure an effective and legally appropriate response. This article covers three aspects of the policy debate: the experience in one state from a legislative perspective, a discussion from an academic viewpoint, and one example of the role of enhanced powers from the response perspective.

The terrorist attacks of September and October 2001 brought home the reality of bioterrorism in addition to accelerating work already underway to strengthen the nation's public health system. Legal preparedness is a core component of comprehensive public health preparedness because laws define the powers and duties of public health agencies to prepare for and respond to terrorism and other grave threats to health. As part of their commitment to addressing those threats, many states assessed their existing legal authority in the months following the attacks and weighed the need to revise and update that authority.

This article features scholarly commentary and insights from policy makers and health leaders who have engaged in reviewing their states' legal preparedness to deal with potentially catastrophic public health emergencies, including states that have considered and enacted legislation to improve their preparedness and response capacity.

The Current Status of Bioterrorism Laws

The CDC had been concerned with and focused on bioterrorism preparedness for several years—well in advance of the events of September and October 2001. However, many state laws dealing with emergency health powers have not been reviewed in over a generation. In fact, many emergency health laws consist of only one sentence stating that the health officer in an emergency may take whatever actions he/she deems necessary.

Part of the reason that these laws have not been reviewed is the success of public health in dealing with infectious diseases. 1954 is a year in which two ships passed in the night—the creation of the Salk Polio vaccine (ending the need for community-wide interventions, such as closing of swimming pools and summer camps) and the U.S. Supreme Court decision in *Brown v. Board of Education* (signaling the beginning of court intervention in the name of individual rights).[1] As part of a broad effort to strengthen the country's preparedness for bioterrorism and other public health emergencies, CDC requested that legal experts at Georgetown and Johns Hopkins Universities develop a draft model law.[2] The Draft Model State Emergency Health Powers Act, which was fashioned out of existing state laws, was designed to assist states in reviewing their emergency public health powers. The draft covers reporting of disease cases, quarantine, vaccination, protection of civil liberties, property issues, infectious waste

disposal, control of healthcare supplies, access to medical records, and effective coordination with other state, local, and federal agencies.

Maine's Actions as One Approach to Updating Bioterrorism Laws

Model statutes are "social software"—one should run a problem through them to see if the outcome will function as an appropriate algorithm. The Draft Model State Emergency Health Powers Act served as a significant checklist for Maine. Maine ran problems through the draft model act and existing law, comparing outcomes.

Maine used the draft model act to review the following issues:

1. access to information;
2. adequacy of disease reporting requirements;
3. property issues (condemnation authority to use private property on a temporary basis with compensation and closure of facilities deemed a public nuisance without compensation); and
4. management of persons (power to compel vaccinations, isolate infected individuals, quarantine exposed persons, due process review).

The distinctions in the draft model act between condemnation and nuisance abatement were particularly well framed and concise. The draft model act struck an appropriate balance between individual rights and the public good.

Maine's quarantine laws were particularly out of date. Concerns raised in the State Judiciary Committee by both the extreme right (concerned about "big government") and the extreme left (concerned about civil liberties) meant that Maine did not use the draft model act as a legislative template. Rather, Maine adopted a highly individualized due process review, similar to the review used for mental health commitment cases, that may not be suitable in a mass response situation. While the Governor may still declare an emergency, the State adopted very tight deadlines requiring a due process hearing that must occur within 24 hours, based on clear and convincing evidence. Unfortunately, in a mass response situation, the statute would require that an immense number of judges' hold hearings around the clock.

An Academic View of Legal Issues Associated with Bioterrorism Preparedness

An academic has the luxury of not being on the front lines; it is far easier to be a critic than a public official charged with protecting the public health. Nevertheless, it is important to play the critic's role because preparedness requires not only vigilance but also deliberation and humility.

There is no doubt that there is a critical role for law and public health lawyers in preparing for bioterrorism or any other public health emergency. Law is an essential tool for public health. Law sets the structure within which public health officials, regulators, and private citizens act to protect the population's health. Law can impede that process—as has often been the case—or it can enhance it—as we hope will be the case. But the recognition of the importance of law to preparedness should not lead to unrealistic expectations about the ability of laws to protect the public health, nor should it neglect the ways in which laws may undermine health or impede other goals and values.

The Draft Model State Emergency Health Powers Act is perhaps most notable for its attempt to provide governors with the authority to declare a public health emergency and undertake drastic actions in response. Recognizing the severe infringement to civil liberties that such authority might entail, the drafters have attempted to provide due process protections for individuals who are isolated or who otherwise lose their rights.

Is an enhancement of emergency powers really necessary? And will the powers be effective? Or will they, instead, provide the justification for the deprivation of liberties in unnecessary circumstances? Times of fear and terror have often, if not

always, led to what hindsight teaches were unnecessary and ineffective deprivations of individual rights, especially to the most vulnerable and marginalized communities. Can we be sure that enhanced emergency powers will not erode the trust that public health will need when and if a crisis arrives? Contemporary efforts such as the draft model act attempt to provide due process rights. Due process is critical—but how realistic is it in a time of crisis and mass detention? And how meaningful can it be when the emergency powers themselves are essentially not reviewable? As lawyers, we need to be careful not to oversell the ability of procedures and hearings to provide safeguards for the powers we promote. While process is critical, it may not be sufficient if greater structural and political safeguards do not exist.

Reliance on new laws and emergency powers may, in fact, give us a false sense of security. While laws may be essential to public health, they accomplish little without resources, personnel, implementation, and enforcement. The danger today is that people, especially those of the elected variety, faced with a budget crises and competing demands for resources, will take comfort that they have prepared for bioterrorism by enacting emergency laws. But, of course, emergency laws by themselves will do little good. For example, a law clarifying the terms of quarantine not only does nothing to prevent bioterrorism, but it does nothing to contain it if the public health authorities lack the resources to actually detect an attack, initiate a quarantine, enforce it, and provide care for those detained. To be sure, the newly signed federal bioterrorism law will provide states with needed funds for training and equipment, but in a time when states are chopping core public health budgets, there remains a real danger that too much faith will be placed in enacting a law that costs nothing more than the paper it is printed on.

Related is the problem that emergency laws and much of legal preparation have focused on containment, rather than prevention. The new federal law takes some important steps toward enacting a prevention strategy by tightening the regulations pertaining to possession of pathogens and increasing inspection of the food supply, but it remains troubling that so much focus of legal preparation has been on containment, rather than prevention. In short, emergency laws themselves do little to prevent a problem. Indeed, in the history of public health, laws that created sanitary public water supplies were probably far more critical to protecting the public's health than laws that isolated individuals.

In addition, once laws are on the books, they often turn out to be far more ambiguous than their drafters ever dreamed. While it is true that many existing public health laws are old, disjointed, out of date, and confusing, we need to be cautious in assuming that wholesale revisions can clear up the mess. In our legal system, we only "know" the law as it is practiced and interpreted over years of use and litigation. Any new law, whether it be a new federal regulatory statute or a new state emergency powers law, will arouse uncertainty and invite litigation the first time it is taken out of the drawer. This is not an advantage when you are seeking to legislate for catastrophe.

Reform efforts should probably be incremental. While model acts can be useful to provide a template for discussion for legislators and regulators in individual states, states should be wary about adopting new laws *en toto*. Instead, states should recognize the value of maintaining, as much as possible, established practices and precedent in their own states. Reforms should be narrow, well tailored to their needs, and well suited to fit within the parameters of the legal system. Likewise, the process of reviewing and modifying existing statutes and regulations should not be limited to bioterrorism, but should focus on public health problems more broadly. Indeed, an excessive focus on the catastrophic may well lead to legal language that is confusing or inapt for more mundane, but more likely problems.

Legal efforts should focus more on actual prevention than on crisis management, more on structural reform than on the deprivation of individual rights. This means we may need to think more creatively about the way that law can work to reduce the potential for bioterrorism.

Different modes of regulation of relevant industries, such as the agricultural and pharmaceutical industries, need to be considered. Hence, public health law needs to break out of an early 19th century model that focused on the regulation of the individual and move to a different model—one that relies on structural organization and the establishment of useful incentives to reduce risks.

As lawyers, we also need to give some serious thought to the jurisdictional tangles that plague public health law. The complex and at times confused relationships among the federal government, states, local authorities, and myriad federal and state agencies present a significant problem both to prevention of bioterrorism and to more run-of-the mill public health issues. Coordinating committees and training sessions are useful here, but as lawyers we need first to understand the jurisdictional web and then to think about ways of clarifying it. Legislation may be relevant here, but we also may need to educate judges about the importance of public health and the need for complex collaboration.

Finally, lawyers need to work more closely with public health officials to help them understand and navigate the laws and legal obstacles that exist. We need to help them understand both the power and the limits of law, just as we need to understand the goals, tools, and language of public health. We can create truly collaborative relationships, so that whether we are regulating an industry, investigating a possible outbreak, or responding to a threat, public health professionals, law enforcement officials, prosecutors, and regulators can work together, understand each other, and do as much as can be done together to safeguard the health of the public.

Issues Associated with the Smallpox Debate

Just as a displayed slide pertaining to a smallpox patient is more graphic than a chest x-ray of an anthrax patient, so the smallpox vaccine debate is more emotional and intensely personal for participants than the anthrax debate.

The anthrax exposures caused by five contaminated letters led to massive confusion. The five letters led to the placement of 33,000 people on antibiotics in four regions of the country. Furthermore, the knowledge base concerning the dissemination of anthrax proved to be wrong.

Because smallpox does not exist in man, its dissemination will be purposeful and may involve novel exposures. Because even one case of smallpox will signal a national emergency, the President will be immediately alerted. The public health response to smallpox will also be different from the response to anthrax, which is not communicable person-to-person and is therefore more similar to a chemical exposure.

It is important to know the legal ground rules in advance of an emergency. It will be necessary to brief the public, in multiple languages, on the nature of the disease and how to respond. There is also a need for a clear national recommendation on vaccination. In an emergency, public health officials will be called upon to deal with a variety of hoaxes and people who are concerned but not sick. The public will also need to be informed about illegal prescriptions and inappropriate use of antibiotics.

The public health response to a smallpox release will require trained vaccinators. Vaccinators, however, may be reluctant to participate if they are subject to legal liability. The issue of who pays for medical treatment in the case of vaccine complications must also be resolved. The smallpox vaccine is currently classified as an Investigational New Drug, a classification that raises research implications because each state maintains a separate Institutional Review Board overseeing research protocols. The smallpox vaccine also raises safety concerns because of the large number of immuno-compromised people and the possibility of inadvertent auto-inoculation in the eye or other parts of the body. In the event of a release, moreover, medical decisions will have to be made about whom to quarantine and isolate.

Conclusion and Closing Comments

There is a need for greater debate and exchange of information about the public health

response to a release of smallpox or other highly infectious disease. Topics to be discussed at the state and national levels include:

1. communication of coherent public health messages to the public;
2. the role of the media;
3. legal immunity of vaccinators;
4. the imposition of quarantine by federal as opposed to state officials; and
5. legal preparedness across multiple state jurisdictions. There is also a need for a profound civil liberties debate at the community level, a debate that should involve legal bar associations and other vested interests.

The threat of smallpox, which is less contagious than measles, needs to be placed in perspective. Although Americans are not tolerant of death, our society has dealt with epidemics in the past, including Spanish Flu in 1918. Thoughtful decisions will need to be made about closing schools, advising the public to remain at home, and delivering necessary services. There are also historical lessons to be learned from pandemic flu and the smallpox eradication campaign that relied primarily on the "carrot" of curing disease rather than the "stick" of isolation and quarantine. Nonetheless, it is important to keep emergency public health powers in reserve should the need arise.

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The Power to Act: Two Model State Statutes

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ABSTRACT

Enabling statutes for state and local public health agencies set forth their powers and duties and provide the legal basis for their work. Obsolescence, inconsistency, and inadequacy may render some public health laws ineffective or even counterproductive. Reforming state public health law can improve the legal infrastructure that supports public health systems in responding to bioterrorism and other public health threats. Two legal tools available to assist the process of establishing a strong legal foundation for public health practice are the Model State Emergency Health Powers Act, developed in 2001 by the Center for Law and the Public's Health, and the Model State Public Health Act, currently under development by the Turning Point Public Health Statute Modernization National Collaborative. These model acts can serve as guides for assessing current state public health law, and they provide example statutory language for use by those working to update their laws. That strong state public health law and model public health acts serve as resources for law reform is recognized by local health officials and state legislators as well as by state public health officials. Lessons learned from recent experiences with crafting and introducing legislation based on the Model State Emergency Health Powers Act can prove useful in the future to those working on public health law reform efforts in their states.

Legal preparedness is one important aspect of a public health agency's ability to prevent or respond to a public health threat. Legal preparedness requires that (1) state and local public health agency officials must have the legal authority necessary to take appropriate action; (2) public health officials must have access to legal counsel; (3) public health officials and attorneys must have training in public health law; and (4) public policy makers must have access to science-based information to inform decision-making.

This article introduces readers to legal tools available to address the issue of establishing legal authority. These tools will assist agencies with establishing a strong legal foundation for public health practice through assessment and reform of public health statutes. Discussion centers on two model laws: (1) the Model State Emergency Health Powers Act developed in the fall of 2001 by the Center for Law and the Public's Health at Georgetown and Johns Hopkins Universities in response to the events of September 11 and the subsequent anthrax attacks; and (2) a comprehensive Model State Public Health Act currently under development by the Turning Point Public Health Statute Modernization National Collaborative.

The Need for Law Reform

Law has long been considered an important tool of public health. However, problems of obsolescence, inconsistency, and inadequacy may render some public health laws ineffective or even counterproductive. Reforming state public health law can improve the legal infrastructure underlying a response to bioterrorism and other emerging threats.

State public health statutes frequently are outdated, built up in layers during the Twentieth Century in response to each new disease threat. Consequently, these laws often do not reflect contemporary scientific understandings of disease (e.g., surveillance, prevention, and response) or legal norms for protection of individual rights. When many of these statutes were written, public health sciences such as epidemiology and biostatistics were in their infancy, and modern prevention and treatment methods did not exist.

At the same time, many existing public health laws pre-date the vast changes in constitutional (e.g., equal protection and due process) and statutory (e.g., disability discrimination) law that have transformed social and legal conceptions of individual rights. Failure to reform these public health laws may leave public health authorities vulnerable to legal challenge on grounds that the laws are unconstitutional or preempted by modern federal statutes. Even if state public health law is not challenged in court, public health authorities may feel unsure about applying old legal remedies to modern health threats.

Health codes among the fifty states and territories have evolved independently, leading to profound variation in the structure, substance, and procedures for detecting, controlling, and preventing disease. Ordinarily, different state approaches are not a problem, but variation could prevent or delay an efficient response in a multi-state public health emergency. After all, infectious diseases are rarely confined to single jurisdictions; rather, they pose risks within whole regions or the nation itself. Coordination among state and national authorities is therefore vital, but it is undermined by disparate legal structures.

Many current laws not only provide insufficient authority to act, but they might also actually thwart effective action. Many state statutes do not facilitate surveillance, and they may even prevent monitoring. Similarly, many states do not require timely reporting of certain dangerous ("Category A") agents of bioterrorism such as smallpox, anthrax, plague, botulism, tularemia, and viral hemorrhagic fevers. At the same time, states do not require and may actually prohibit public health agencies to monitor data collected in the health care system. Moreover, private information that might lead to early detection (e.g., unusual clusters of fevers or gastrointestinal symptoms) held by hospitals, managed care organizations, and pharmacies may be unavailable to public health officials.

Of course, coercive powers are the most controversial aspects of any legal system. Nevertheless, they may be necessary to manage property or protect persons in a public health emergency. The law must provide the authority needed, with fair safeguards, to manage property and protect persons in order to contain a serious health threat.

The Model State Public Health Act

The Robert Wood Johnson Foundation, in partnership with the W.K. Kellogg Foundation, implemented an initiative in 1996 to support state and community efforts to strengthen their public health systems. Titled "Turning Point: Collaborating for a New Century in Public Health," this project culminated in the development of strategic public health system improvement plans for funded efforts.

Both foundations supported a second phase of Turning Point, funding implementation of priority strategies in the plans of initial grantees. The Robert Wood Johnson Foundation also identified five topics that had emerged as common issues across multiple states during the planning phase, and it provided additional implementation funding to address topics. Five national workgroups, called the "National Excellence Collaboratives," have been funded and are working to (1) modernize public health statutes, (2) create accountable systems to measure performance, (3) utilize information technology, (4) invest in social marketing, and (5) develop leadership. The Collaboratives bring partners from Turning Point states and communities together with national partners to assess the current landscape in each area and to develop models to be used as tools in public health system development.

The Turning Point Public Health Statute Modernization National Excellence Collaborative began meeting in April 2000. The vision Collaborative partners agreed to work toward is one of "clear, concise, up-to-date laws that support improved health and strong public health systems." The Collaborative determined early on that the one product it could develop to achieve this vision was a model state public health law. The model could help states assess current statutes that provide the legal authority for public health practice and could provide sample statutory language for strengthening these laws. Thus, the Collaborative defined the mission as "to transform and strengthen the legal framework for the public health system through a collaborative process to develop a model public health law."

Partners participating in the Statute Modernization Collaborative include state and community representatives from the Turning Point states of Alaska, Colorado, Nebraska, Oregon, and Wisconsin. The Centers for Disease Control and Prevention and the Health Resources and Services Administration are the two federal agencies participating in this effort. Other national organizations represented in the Collaborative include the National Conference of State Legislatures, the National Governors Association, the American Public Health Association, the Association of State and Territorial Health Officials, the National Association of County and City Health Officials, the National Association of Local Boards of Health, and the Institute of Medicine. The Collaborative contracted with Lawrence Gostin, Director of the Center for Law and the Public's Health, to provide the legal expertise to evaluate current law and draft the Model Act.

The plan for the creation of the Model State Public Health Act (MSPHA) took the group initially through a one-year development and assessment phase. The report resulting from that phase, the *State Public Health Law Assessment Report*, is available at <www.turningpointprogram. org>.

The Collaborative next began the work of drafting the Model Act by deciding what the Act would and would not do and then identifying the framework for the Act (i.e., what elements would be included and how it would be structured.) The Collaborative agreed that the MSPHA would set forth statutory language concerning public health administration and practice. That language would be consistent with modern constitutional, statutory, and case-based law at the national and state levels, and it would reflect current scientific and ethical principles underlying public health practice. It would focus on the organization and delivery of essential public health services and functions based on the statement Public Health in America (Public Health Functions Steering Committee, 1994). It would focus on the traditional powers of public health agencies, but it would be framed within a modern public health infrastructure. Finally, it would seek to balance the protection of public health with respect for individual rights.

It is important to understand the limitations of the Act in addition to understanding what the Act will do. The MSPHA will be relevant to but will not cover such distinct areas of law as mental health, substance abuse, and regulation of the health care industry. It will not include model provisions for laws that impact the public's health, such as seat belt provisions, DUI laws, and tobacco control regulations. It will not include extensive language concerning areas of law traditionally covered elsewhere in state statutes, such as tax provisions and administrative procedures. And it will not specify regulatory details.

The Collaborative is now in the process of drafting the MSPHA. The first draft is slated for completion and broad dissemination for public review and comment in late 2002. The Collaborative will spend six months soliciting comments and another six months compiling, reviewing, and incorporating the comments. The Act is to be finalized by October 2003. A current draft of the Model State Public Health Act is available at the Turning Point Initiative's Web site <www.turningpointprogram.org>.

The Model Emergency Health Powers Act: Process and Content

With little initial public and political impetus for speedy law reform, the Turning Point Public Health Statute Modernization Project began in 2000 with a four-year time horizon. Following the events of September 11th and October 4th, however, the need for law reform captured the attention of political leaders. On October 6, 2001, the CDC contacted one of the grantees, the Center for Law and the Public's Health, and asked it to coordinate the generation of a draft Model State Emergency Health Powers Act (MSEHPA). Driven by concerns that governors and state legislators would need guidance in the development of new public health law in time for the approaching legislative sessions, CDC requested a turnaround time of three to four weeks for development of the MSEHPA. That began an intensive drafting process in collaboration with members of the National Governors Association, the National Conference of State Legislatures, the National Association of Attorneys General, the Association of State and Territorial Health Officials, and the National Association of County and City Health Officials. Drafting of the MSEHPA was completed within the development timeframe, and to date, legislative bills based on the MSEHPA have been introduced in 33 states. Fifteen states have already enacted a version of the Act.

The MSEHPA has been developed by use of an open and deliberative process. Federal agencies such as the CDC and the U.S. Department of Justice provided intellectual support, as did high-level staff of state governors, legislators, attorneys general, and health commissioners. The Center for Law and the Public's Health received thousands of comments from national organizations, academic institutions, practitioners, corporations, and the general public. The MSEHPA has been widely discussed in the media. Despite the rigorous and inclusive process, the MSEHPA has provoked criticism from a civil liberties and property rights perspective.

The MSEHPA (available at <www.publichealthlaw.net>) supports the vital functions of planning, surveillance, management of property, and protection of persons, while safeguarding personal and proprietary interests. Planning and surveillance would be implemented immediately, but the measures affecting property and persons would be triggered only after a state's governor declares a public health emergency.

The Value of Strong State Public Health Law—a Local Perspective

From the perspective of a local public health director, a strong state public health law provides a number of basic supports for the foundation of the local public health infrastructure. First, everyone knows ahead of time what needs to be done, how it is to be done, and whether the capacity exists to do what is needed. Too many times, local public health directors rely on general statutes that give only broad powers and that must be interpreted in a manner that provides the needed authority.

Second, a strong statute defines roles and responsibilities, regardless of the state/local structure. The state/local structure currently varies across the nation, with some states, such as California, having almost everything done at the local level, and others, such as New Mexico and Maine, having everything done at the state level in the absence of any local health departments. Whatever the state and local structure, a strong statute defines responsibilities before a crisis occurs and ensures that programs and crises are managed at the level of service closest to the people.

Third, a strong state law provides a tool to promote awareness of potential legal issues among policy makers, public health officials, local legal counsel, and attorneys general, and it provides an opportunity for them to gain consensus on those issues before a crisis occurs. The MSEHPA provides a template to ensure that the necessary components are in the law and that there is a consensus decision to include, or not include, aspects of law depending on the structure and needs of the individual state.

A strong state public health statute also is the foundation for the decision-making process and identification of priorities. It defines how to conduct business. It provides the road map to transition from the daily routine work to the crisis work that must be done in an emergency. A real life example from one state county illustrates the deficiencies of current law. A patient was determined to have active TB but refused to comply with the local public health order to remain in isolation. It took six weeks of work with the county attorney and the state health department to develop a control mechanism within the bounds of current laws. During this six-week period, an active TB case wandered the county, and county counsel was legally unable to support the county agency to contain or restrain the person. This was an isolated instance. But what if it had been an emergency and a large number of people had been involved?

Finally, a strong state law provides the opportunity for state and local partners who are working in public health law improvement to ask the right questions. It also provides a tool to keep the cost of developing individual state statutes to a minimum.

Why look at statute modernization? From the perspective of a local health official, there are three reasons:

1. Clear public health law is essential to fulfill the expectations of the public. The local public expects that its public health agency can take the necessary action to provide protection from communicable diseases. However, without clear legal authority, that agency cannot meet that expectation.
2. Historically, public health officials have learned to fulfill their responsibilities by working longer and harder with the same or even fewer resources. Clear law will be an additional resource that will allow an agency to meet its responsibilities in a more efficient manner and thereby better serve the public.
3. Clear public health law can save lives. Public health officials who know ahead of time exactly what can be done and how it can be done can react to a public health incident more quickly. Unfortunately, the daily operation of categorical programs typically stretch a department so thin that public health agencies do not have the staffing resources to play the "what if" game and think through what could happen and what needs to be done to prepare for every type of crisis. A clear public health law will help define the necessary staffing levels and promote the planning.

Model Public Health Law and the Political Process

The Model State Emergency Health Powers Act serves as a useful checklist for a state legislator, presenting key issues that state statutes should address. Among them are the following:

1. Availability of information: Do officials have statutory power to obtain the information they need to evaluate public risks? Can they review private records and gain access to confidential information as necessary to do their jobs? Are there safeguards in place to preclude the release of information beyond those who have a need to know?
2. Reporting: Are rules in place to require all health care providers to report information significant to the evaluation of public health risks? Do reporting rules apply not only to hospitals and medical practitioners but also to nursing homes, pharmacies, veterinary clinics, and others who may encounter signs of impending risk?
3. Quarantine: Do public health officials have the power to evacuate homes and commercial properties, to close down businesses if necessary, and to exclude people from all areas of suspected contamination?
4. Takings: Do health officials have the power to take property for temporary or permanent use in a public health emergency? Is there a system in place to provide compensation if the owner suffers a loss of use or value because of the public exigency?

5. Treatment: Does the public health official have power to compel people to accept treatment and vaccinations to meet a public health emergency? Such powers include the following areas:
   a. Quarantine: Does the health official have power to quarantine people who have been exposed to contagious disease?
   b. Isolation: Does the official have power to isolate those who have symptoms of the disease?
   c. Civil rights: Are individual civil liberties protected by appropriate administrative and court procedures? Are the powers limited in duration and scope? At what point must officials petition the court to confirm an order if a citizen resists or disagrees? What rights of appeal do citizens retain? Is there adequate due process to enable citizens to terminate or suspend a temporary order? Are officials required to propose less restrictive alternatives when those who are subject to the order resist compliance?

Before bills on these subjects are introduced, it is wise to review them with interest groups such as the medical societies, hospital associations, and the civil liberties union to determine whether objections can be dealt with in the drafting stages. An advantage of relying on the Model Act is that it has already been carefully reviewed and amended to suit the concerns of hundreds of interested stakeholders.

No matter how carefully these provisions are drawn and presented, the level of resistance may prove surprising to sponsors of the bill. Lawmakers and citizens who share deep concerns about the resulting infringement of human liberty, the deprivation of property rights, the loss of privacy, or the enhanced power of government are likely to express significant reservations. Objections will not follow predictable ideological lines. Some resistance will come from the left and some from the right.

Governmental power and emergency measures that people may have found necessary and acceptable during the plague years of the First World War are no longer easily supported by a citizenry sensitized to civil rights by the change in our culture that transpired during the last half of the Twentieth Century. Nevertheless, the events that occurred in the fall of 2001 remind us that it may be necessary—even in our free society—for government to hold in reserve certain emergency powers to be exercised in a constrained and appropriate way when necessary to protect society at large from threats that are difficult to fathom or impossible to imagine in tranquil times.

Conclusion

Without clear legal authority, public health officials cannot take action to protect the public's health. Model public health law is a resource for strengthening the public health infrastructure. With careful planning and a public process that engages a diverse constituency, public health officials, in partnership with legal counsel and state legislators, can work proactively to ensure that an adequate legal foundation for public health practice is in place. The two models discussed in this article can serve as tools for those striving to ensure that governmental public health agencies have sufficient legal powers to act in the best interest of the public to protect and promote health in their states and communities.

Public Health Emergencies and the Public Health/Managed Care Challenge

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ABSTRACT

The relationship between insurance and public health is an enduring topic in public health policy and practice. Insurers share certain attributes with public health. But public health agencies operate in relation to the entire community that they are empowered by public law to serve and without regard to the insurance status of community residents; on the other hand, insurers (whether managed care or otherwise) are risk-bearing entities whose obligations are contractually defined and limited to enrolled members and sponsors. Public insurers such as Medicare and Medicaid operate under similar constraints. The fundamental characteristics that distinguish managed care-style insurance and public health become particularly evident during periods of public health emergency, when a public health agency's basic obligations to act with speed and flexibility may come face to face with the constraints on available financing that are inherent in the structure of insurance. Because more than 70% of all personal health care in the United States is financed through insurance, public health agencies effectively depend on insurers to finance necessary care and provide essential patient-level data to the public health system. Critical issues of state and federal policy arise in the context of the public health/insurance relations during public health emergencies. These issues focus on coverage and the power to make coverage decisions, as well as the power to define service networks and classify certain data as exempt from public reporting. The extent to which a formal regulatory approach may become necessary is significantly affected by the extent to which private entities themselves respond to the problem with active efforts to redesign their services and operations to include capabilities and accountability in the realm of public health emergency response.

The relationship between health insurance and public health is an enduring topic in public health policy and practice. As the United States health system has been transformed from a loose confederation of insurers and independent health care professionals and institutions to one in which insurance and health care exist in tandem as part of formal risk-bearing managed care arrangements, additional challenges have emerged. These challenges become particularly critical to understand in the context of public health emergencies.

Following a general discussion of federal and state policy issues related to the integration of public health and health insurance activities during public health emergencies, this article describes experiences of one of the nation's leading managed care organizations in preparing for such situations. However, even though the focus here is on managed care arrangements in a public health emergency context, most of the issues associated with the relationship between managed care and public health during public health emergencies would arise in any form of

health insurance, public or private. At the same time, because managed care integrates health coverage and health service delivery, managed care-style insurance arrangements raise certain issues unique to this form of health insurance.

Federal and State Insurance Policy and Public Health Emergencies

The general issues that can arise as part of the interaction between health insurance and public health have been explored over the years.[1, 2] To be sure, managed care and other insurance arrangements share certain common attributes with public health, including a population-wide orientation, the integration of financing and health care in the case of managed care and those public health agencies that continue to furnish personal health care services, and an emphasis on preventive care. At the same time, health insurance and public health differ fundamentally at their core. Public health agencies operate in relation to the entire community they are empowered by public law to serve, without regard to the insurance status of community residents and regardless of whether the health services and public health safeguards needed by the community amount to insured benefits. Insurers, on the other hand, whether traditional indemnity or service benefit plans or modern managed care-style arrangements,[3] are risk-bearing entities whose obligations are contractually defined and limited to enrolled members and sponsors. Only to the extent that public policy intervenes through regulation or other legal standards do these contractual terms get defined in a broader community benefit context. Public insurers such as Medicare and Medicaid, whether operating traditionally or through managed care contracts, are governed by laws that operate in a manner similar to the insurance contract, creating a legal right to coverage in eligible persons but limiting program obligations to covered benefits furnished to eligible individuals. Only when public law is specifically structured to address issues that transcend specified benefits for defined populations (such as Medicare and Medicaid requirements related to disproportionate share payments to hospitals serving high levels of uninsured and publicly insured persons) does either program tend to define its obligations in relation to the broader community.

In sum, public health agencies are organized and administered with a community-wide orientation and are expected (and at least theoretically empowered) to be sufficiently flexible in their operations to be able to respond on a community-wide basis to unanticipated and rapidly emerging needs and threats. The duties of public health agencies are conceived of broadly. At the same time, while communities may have broad expectations of public health agencies, no individual member is legally entitled to any defined benefits. Private health insurance, on the other hand, has at its core a highly formal contractual design that is deliberately not flexible and elastic but is instead designed to create legal guarantees in eligible persons; thus, the lack of flexibility is offset by enrolled members' contractual entitlement to coverage for specified services. Medicare and Medicaid tend to be more broadly conceived and organized than commercial insurance, with missions and mandates that transcend the bounds of commercial enterprises.[4]

The fundamental characteristics that distinguish managed care and public health become particularly evident during periods of public health emergency, when a public health agency's basic obligations to act with speed and flexibility to meet the health threat that confronts an entire community may come face to face with the constraints on available financing that are inherent in the structure of insurance. Because more than 70% of all personal health care in the United States is financed through public and private insurance arrangements, public health agencies can find themselves without the ability to control the allocation of financial resources necessary to support emergency and post-emergency medical and health treatment. Public health agencies also may find that much of the individual-level data and information essential to the identification of

persons exposed to public health threats or the monitoring of treatment are not available because insurers that pay for the services consider the data and information proprietary. Finally, the authority to set the rules and parameters of treatment and coverage, as well as the practice standards and service locations that should guide the performance of the health system during times of public health emergency, may lie with the insurers that control the financial resources, rather than with the public health agencies that need to manage the emergency in the context of the entire community.

An example of how the principles of insurance can come into direct conflict with public health imperatives arose in Milwaukee, Wisconsin in the late 1980s, when a measles outbreak affected the community and claimed the lives of several children. When epidemiologists investigated the causes of the outbreak, they discovered widespread under-immunization among the city's Medicaid population, and they further determined that the state's managed care contracts excluded immunization services. Because participating Medicaid managed care organizations were not contractually obligated to immunize their enrollees, infants and children went unvaccinated, and the epidemic became possible. Subsequent contracts were amended to add immunization coverage, but the mere fact that immunization is one of the most cost-effective and essential public health investments was not sufficient to ensure that insurers would furnish the coverage of their own accord.

Every state regulates private health insurance contracts to a greater or lesser degree.[5] At their core, however, insurance agreements are highly structured private contractual instruments that spell out in the most precise terms possible the scope of the coverage that an insurer is legally obligated to provide. With limited exceptions for specified preventive and primary services, coverage tends to be restricted to insurable medical events and specified diagnostic and treatment services that are considered medically necessary as defined by the insurer. Managed care-style health insurance plans add another layer of contractual limitation to coverage. In managed care-style plans, coverage is further restricted to treatment furnished by participating network providers selected and overseen by the insurer. Out-of-network services (including services related to medical emergencies) may be either completely excluded or covered only with higher cost-sharing or the prior approval of the insurer. In the absence of regulation, insurers retain the contractual power to define the content of covered treatments, select the practice guidelines and utilization review parameters they will follow, and in the case of managed care, select their networks.

In approaching the relationship between managed care and public health in the context of public health emergencies, state and local health policy makers are confronted with the basic decision that characterizes the relationship between public health and private interests: the extent to which the relationship should be formally described in statute and regulation as opposed to an approach that relies heavily on voluntary collaboration and perhaps incentivization. But as the Milwaukee measles case illustrates, collaboration between public health and insurers inevitably must have implications for the scope and structure of the insurance contract itself, because the law does not invite informal efforts to alter or revise a contract of coverage to furnish what was not specified. Thus, at some point, at least where the broad public policy considerations that lie at the base of public health emergency laws come into play, it is important to consider the public policy matters that arise in the insurance/public health emergency context. Of course, a government may elect to bypass the issue of coverage and directly bear the costs, out of general or dedicated revenues, associated with treating a population both during and following the immediate period of a public health emergency. But while government may use direct financing for certain services and activities, public health emergencies can be expected to have costly and long term physical and mental health consequences, thus making ongoing direct government financing through "extra-contractual" coverage less feasible.

Because the American health care system is built on an expectation that necessary medical care will be financed through insurance coverage (indeed, virtually all states, for example, now define "prudent layperson" emergencies as a covered benefit in state-regulated managed care contracts), indefinite reliance on direct government financing would appear to be at odds with the operation of the medical care system itself. At some point, it becomes important to reconcile insurance financing and public health principles.

Some basic issues arise at the state policy-making level when officials are formulating policy regarding the relationship between public health and managed care in the context of public health emergencies:

1. A number of distinct issues arise as states formulate public policy in the area of insurance regulation for public health emergencies, including
   a. Should insurers and managed care organizations be permitted to exclude from coverage the diagnosis and treatment of conditions related to a public health emergency, defined either generally or more specifically in terms of acts related to terrorism? Since the World Trade Center and Pentagon attacks of September 11, 2001, the issue of exclusionary clauses for acts of terrorism has arisen among property and casualty insurers. Therefore, it is likely that this issue could arise in the context of medical coverage. The question of coverage, of course, has many sub-parts. If exclusions will be permitted, what types of exclusions? Would total exclusion be permissible? Would coverage up to some stop-loss be required? How broadly could an insurer define an exclusion? Could an entity retain the sole power to determine that a condition is related to a declared public health emergency and thus excluded, or would a state insurance agency determine the exclusion and when and under what conditions the exclusion can be permitted to operate?
   b. Should state law mandate a special public health emergency benefit that details the level, scope, and amount of physical and mental health service coverage that would be required in the event of a public health emergency? If so, what would the benefit design look like in terms of prophylactic, diagnostic, treatment, and follow-up care? Who would have the authority to determine the existence and duration of the emergency? Would mental health parity considerations apply to this supplemental coverage?
   c. In the event that coverage is secured through a network of participating providers, as in the case of managed care-style arrangements, should out-of-network coverage be mandatory in the event that certain emergency and other medical care facilities have been designated? Who should set the rate of payment and policies regarding the scope of covered procedures for conditions arising from the emergency?
   d. In a public health emergency context, who should make decisions regarding the medical necessity of care? Are there certain evidence-based practice guidelines that should be applied to decide coverage?
   e. What is the status of patient- and member-level data associated with treatment and health status when these data are generated through the insurance claims process during a period of declared public health emergency? Which data should be treated as reportable and notifiable, and thus available to public health agencies, and under what circumstances?
   f. How should the benefit be financed? Through a general premium surcharge? Simply as an added factor in determining basic premium rates?
2. The issues that arise in state regulation of insurance are not limited to private coverage. The same general types of issues would apply to a state's Medicaid and State Children's Health Insurance programs (SCHIP), as well as to other public health insurance programs administered by state government. What benefits

should be available to beneficiaries during periods of public health emergency? The issue is particularly critical in the case of adult coverage. For example, most state Medicaid programs do not cover vaccines for adults and may place deep restrictions on coverage of treatments for mental health conditions. State Medicaid and SCHIP that use managed care style coverage arrangements essentially must make all of the same choices in negotiating their contracts that state officials would need to make in a commercial insurance context.

3. The preemptive effects of federal law dramatically affect the power of state government to make policy in the area of insurance and public health, at least to the extent that those policies relate to the design and administration of health insurance plans.[4] The Employee Retirement Income Security Act (ERISA) imposes powerful limitations on states' powers to regulate employee health benefit plans. Despite recent decisions by the Supreme Court recognizing the primacy of states in matters of medical care and health quality,[5,6] it is difficult to imagine that coverage mandates, even if they took the form of laws that regulate insurance, would not be preempted in the case of self-insured plans that do not involve the purchase of insurance products. The Supreme Court is expected to decide during its 2002-2003 term whether willing provider statutes that mandate the structure of a plan's network for coverage purposes can be saved as laws that regulate insurance. Whether the federal government should set parallel standards for health plans exempted from state law becomes a major issue.

   Although the issue has received less attention over the years, the same problems of preemption apply to Medicare and the Federal Employee Health Benefit plan. Similarly, a federal policy clarification regarding the availability of federal financial participation for supplemental Medicaid and SCHIP coverage in the event of a public health emergency becomes necessary.

4. An underlying issue in any discussion about changing insurance law to respond to public health emergencies is the question of what to do about the more than 40 million uninsured Americans. How should the care of uninsured Americans be managed during public health emergencies? Should direct payment arrangements to institutional and community providers be available? Precedent for this type of national pooling arrangement necessary to the financing of services for persons outside of public and private insurance can be found in the 1986 immigration reform legislation, which established a program of state allotments for medical and other services incident to the legalization of immigrants.

The Insurance Response to Public Health Emergencies: One Insurer's Experiences

Kaiser Permanente, one of the nation's leading insurers and a leader in HMO policies, has as one of its central corporate visions the ability to provide collaborative health care services under all conditions and in the face of any health threat. Specifically, Kaiser defines as part of its mission protecting the community, ensuring ongoing and uninterrupted internal response capability with continuous operations during all events, collaborating with communities and all levels of government, and educating and preparing the community for public health threats. Key lessons that Kaiser officials have learned over the course of practice, in particular as a result of the 2001 anthrax outbreak, are that early diagnosis is critical, that symptoms of a specific threat may present differently, and that normal diagnostic techniques (such as a chest radiograph) may understate the degree of disease. Kaiser officials also came to appreciate the need for dissemination of consistent and accurate information to front line clinicians through daily conference calls, the need for rapid changes in treatment protocols as evidence emerged, the need for continuous revision and updating of key contacts through the emergency

event, and the need to develop treatment and evaluation protocols during the event itself.

Dealing with the anthrax crisis and the company's participation in the National Bioterrorism Wargame of 2001 provided the company with important lessons. The critical lessons for insurers can be summarized as follows:

1. To react quickly, the insurance industry needs a single point of contact with government, but in a federal system, the statutes, policies, and programs for dealing with terrorism typically create multiple points of contact at the agency and governmental levels.
2. Aggressive containment and prophylaxis can limit the spread of disease, but moving too quickly also can consume necessary long term reserve resources.
3. Response plans normally focus at the local level, but bioterrorism is a national problem requiring collaboration across all levels of government.
4. Suspending legal and regulatory constraints might be necessary to meet immediate needs, but it can have serious downstream consequences for both public policy and industry stability.
5. Bioterrorism is an act of war, but the health care industry is not prepared or suited for marshalling a military response.

Given these lessons, a critical step for the industry is preparation of a comprehensive business continuity and threat assessment program. Critical management issues on the business side include systematic planning and risk assessment. On the threat assessment and management side, essential functions are threat policy development, measured responses, and the integration of policies with services. In order to achieve this outcome, Kaiser has pursued an extensive planning and response model that uses work groups addressing clinical concerns, facilities, supply chain, community links, and communications policy.

Examples of the types of threats that Kaiser focuses on in carrying out its program are the release of lethal substances in mass transit systems; hazardous materials spills; explosions, earthquakes, flooding, and power outages; and direct personal or biological attacks. The spectrum of impact on Kaiser ranges from direct to indirect, and the entity prepares its responses to deal with each level of impact.

The outcomes of this integrated and comprehensive planning process have been multiple and varied. These outcomes have included the company's

1. creation of a medical center decontamination protocol and other related activities;
2. creation of medical office decontamination guidelines;
3. development of guidelines for pharmaceutical and trauma supply caches;
4. development of comprehensive protocols for staff;
5. coordination of multi-county syndromal surveillance protocols and collection and analysis systems, with pilot sites established for syndromal surveillance, and the development of an enterprise bioterrorism response plan;
6. refined national and regional corporate planning;
7. participation in state and local advisory committees;
8. development of a disaster readiness intranet site;
9. development of medical protocols for all pathogens defined by the Association for Professionals in Infection Control and Epidemiology;
10. implementation of a voluntary relief fund for employees;
11. carrying out of enterprise-wide disaster exercises and participation in a government funded exercise; and
12. implementation of a standard Hospital Emergency Incident Command System throughout the organization as well as establishment of standardized facility hazard and vulnerability and assessment protocols.

Conclusion

Public health emergencies raise complex issues of public policy in the context of the relationship between public health agencies, on the one hand, and insurers and managed care organizations on the other. The experiences of Kaiser Permanente, a leader in health maintenance organizations, show the extent to which entities that both insure members and furnish health care may need to redesign their business and clinical operations to ensure appropriate response to public health emergencies. The complexities of the insurance/public health interaction also underscore the need for long-term policy development in the area of insurance coverage in a public health context. These issues go beyond who will pay for the medical care that a community might need as part of a response to a public health threat. Because managed care plans (the dominant form of health insurance today) merge health care and coverage, the decision regarding who has the power to decide the depth, scope, and range of coverage during an emergency also has implications for the quality of care itself as well as for access to community-wide information about the course of the threat and its impact on individuals.

In a federal system, the responsibility for these basic decisions regarding health care quality is shared by state and federal governments, thus making the process of answering these questions even more complicated. The issues of coverage also raise the underlying problem of how these services will be financed, both immediately and in the long term. What portion of the medical system's response to a public health emergency ought to be conceived as part of the standard elements of a public or private health insurance plan? At what point do costs become extraordinary and subject to supplemental government funding? These are some of the most important health-related matters that the debate over public health threats will need to confront in the coming years.

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Land Use Planning: Why Public Health Must Be Involved

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ABSTRACT

The way that land is used has a direct impact on public health. Legislators and other with responsibility for land use planning need to be aware of the public health connection and need to promote effective land use planning as a means of improving the public's health. This article discusses the public health/land use connection and the role that local, state, and national legislators can play in promoting land use planning that supports the public's health. It also provides an example of a collaborative local land use initiative aimed at addressing a public health problem in a city and at providing a model that other locations can use in making land use conform to sound public health policy. Finally, it provides an overview of initiatives to promote healthy land use in the New York metropolitan area by Regional Plan Association, a private non-profit planning organization.

The legislative branch at the local, state, and federal levels must get involved in rethinking land use planning's natural relationship to public health. After all, land use has a direct impact on public health through its influence on housing and the natural and social environments in which people live. In order to become involved, legislators must be informed regarding land use planning's impact on public health. Legislators at every level of government have influence on the way land is used. City councils, boards of aldermen, boards of selectmen, and other local bodies have perhaps the most direct influence on land use through land disposition agreements, zoning ordinances, and city plan approval.

At the state level, the legislature sets policy standards for housing developments, playgrounds, parks, school buildings, sidewalks, and other community properties. As an incentive to adhere to state land use policy, a state legislature may also fund many programs that meet standards. At the federal level, Congress allocates money for special programs related to land use. It also establishes spending programs covering such activities as HUD redevelopment, privatization of federal housing projects, establishment of greenways/trail projects, and similar initiatives.

Legislators at all levels have an ability to promote change in land use policy through use of the bully pulpit. They can bring influential people together to learn about the relationship between land use planning and public health and to begin to address the issue as it relates to various settings.

Intervention at New Haven, Connecticut: An Example of Local Action to Promote Effective Land Use Planning to Improve Public Health

A land use planning/public health intervention occurred in New Haven, Connecticut as an outcome of a collaboration that was suggested and technically supported by Milbank Memorial Fund. The collaboration utilized legislative relationships to bring influential people to the table to discuss New Haven's childhood obesity

problem and the means by which land use planning could address this problem.

New Haven's children are more obese than those in the United States as a whole. Recent studies in the city have shown that up to 60% of adolescents are obese. Type 2 diabetes is diagnosed in children as young as 5 in the city, and 40 percent of newly diagnosed cases of diabetes in youth are type 2, a previously rare diagnosis for young people. These youth are at risk of other health problems associated with diabetes by the time they reach their mid-twenties.[1]

New Haven's committee of stakeholders to address the childhood obesity problem in a land use context included the city planner, the community services administrator, school officials, an alderman, a family resource center representative, a child day care commissioner, a pediatrician working with the Department of Health on school nutrition, and others. The committee decided upon a project to reduce childhood obesity in New Haven by proposing low-cost modifications of indoor and outdoor school space in order to encourage school children to increase their physical activity. Much of the work of the project is being carried out by the staff of Project for Public Spaces, an internationally known non-profit organization based in New York City that has worked on other projects involving the redesign of schools and adjacent space. Project for Public Spaces and the Milbank Memorial Fund, an endowed private foundation, agreed to finance the work on the project. The Fund will pay for an intern recruited to work on the project through the City of New Haven City Planning Department. The intern's responsibility will be to coordinate the redesign.

This project will enable New Haven to increase usage of space and physical activity within school grounds and buildings. The Project for Public Spaces will use participatory planning techniques to involve children, teachers, and other members of the community in the process. The following phases describe the planning and implementation steps.

Phase 1: A meeting/brain storming session with key decision-makers and their agents.

Phase 2: On-site user evaluations of three newly built schools grounds.

Phase 3: A pilot project evaluation in one school. Low cost modifications arising from Phase 2 will be tested in one school and their effectiveness evaluated.

Phase 4: A briefing session with users to evaluate Phase 2 and Phase 3.

Phase 5: Evaluation of plans for buildings currently in design.

A mixed group of users (drawn from the onsite evaluation) will become members of the School Construction Advisory Committee (SCAC), and design professionals will review the existing school plans in a one-day workshop. The workshop will start with a video presentation based on footage taken from the onsite evaluations and recommendations. It is hoped that children and other users involved in the evaluation will assume an ongoing role as advisors to SCAC.

Phase 6: Presentation of deliverables to decision-makers.

Key decision-makers and their agents will be presented with recommendations for schools that are newly built or in design, along with a design manual (both video and Web-based) and summary project findings (i.e., quotes and statistics). These will be submitted in draft form for comments.

Broader Dissemination of Results

In consultation with important decision-makers, Project for Public Spaces will aim to leverage the outcomes of the project into a nationwide program on school design and programming. Currently, no national programs in the United States are dedicated to design and management of school premises, and remarkably few regional initiatives exist. The New Haven program could result in the production of a video as a training tool, the production of regular training programs, and further development of the Web-tool kit to include a resource center of images and research. The timetable for production of such training material would be approximately two months. The entire New Haven project should be completed by the end of 2002.

The project, named Healthier School Buildings and Grounds for New Haven, is just one example of how legislative collaboration with a private sector foundation, with city planners, with community leaders, and with government officials brought land use planning and public health together. Participants in the project believe that this project will make a positive difference in the health of New Haven's children and in the health of the children in those communities that choose to replicate this project.

Initiatives of the Regional Plan Association

The Regional Plan Association (RPA) works with communities in the New York metropolitan area to initiate and implement land use projects that promote a healthier environment. The RPA does so through its Healthy Communities for the New York Metropolis (Healthy Communities) project. To date, the RPA has undertaken numerous initiatives.

New Ways to Work and Play: Using The Mill River Corridor to Connect Stamford's Communities

The City of Stamford, Connecticut is making a major public investment in the Mill River corridor with the creation of a new park system in the downtown and with the commitment, in the new Master Plan, to a larger greenway network extending from the Merritt Parkway to the South End waterfront. This Healthy Communities project will leverage the benefits of these investments in several ways:

A. Promote increased activity levels in the disadvantaged and largely minority neighborhoods on the west side of the new Mill River Park, both through recreational opportunities in the park itself and through increased connectivity between the neighborhoods and the new downtown Mill River Park. The project will explore ways of increasing activity levels by promoting pedestrian and bicycle connections to the park, to the downtown beyond, and to the larger greenway network.
B. Provide opportunities for biking, jogging and walking for the employees in the large corporate campuses along Long Ridge Road as well as the residents of the elder care facilities along this corridor.
C. Promote bicycle and pedestrian activity throughout Stamford by linking open space resources and providing alternative modes for journey-to-work.

Green Linkages for Westchester Communities

Westchester County, New York continues to explore ways of balancing intense suburban development with the need for greenways and other alternative ways of connecting cities, towns, and villages. Several greenway opportunities, many based on the historic parkway systems, are playing an increasingly important role. This project will identify strategic connections between the various greenway initiatives and several different kinds of communities in Westchester. The greenway projects will be used to educate local partners on healthy community design and will provide valuable design input for the greenways themselves.

Changing Landscapes in New Jersey: Healthy Communities and Alternatives to Sprawl

New Jersey has just adopted its State Development and Redevelopment Plan, which seeks to promote growth in compact, mixed use centers and protect open space and farmland in the most densely populated state in the nation. While there are currently many progressive ideas relating to concentrated mixed-use development and transit-friendly design strategies, these ideas have yet to be linked explicitly to a healthy communities agenda. This project will explore several ways of leveraging the health agenda to design and implement new alternatives to sprawl development patterns. The project will exploit the fact that New Jersey is a laboratory for virtually every form of urban, suburban, and rural settlement and that a policy framework already exists in

the form of the State Plan, which does recognize the linkage between land use and public health.

The New Jersey Mayors' Institute on City Design

The New Jersey Mayors' Institute on City Design (MICD) provides a two-day retreat for eight mayors to come together with a panel of national experts on community design, public health, and the development process. The mayors present case studies of urban design problems and receive advice from the panel on how to make their communities more livable, walkable, and successful places. Between those discussions, the panelists make presentations on topics such as urban and landscape design, the development process, state resources, and the connection between public health and community design.

The MICD was established by RPA to promote smart growth through better design of communities in New Jersey, empowering mayors with knowledge and a vision to implement high-quality, sustainable community plans to promote more active lifestyles. The goal of the MICD is to educate local officials about state-of-the-art design theory and techniques and to provide mayors with the opportunity to bring a case study to national and state experts for ideas and suggestions. A secondary goal is to create a "fraternity" of mayors with strong design knowledge who can serve as experts to other communities.

The program is modeled on the successful nationwide program sponsored by the National Endowment for the Arts. However, the MICD is unique in closely involving state government and focusing on the special role that design has in public health issues. Panelists and speakers at past institutes have included national experts on urban design and public health issues, including Mayor John Norquist of Milwaukee, Mayor Joseph Riley of Charleston, and Thomas Schmid from the federal Centers for Disease Control and Prevention.

RPA organized the first MICD in 2001 with the assistance of the National Endowment for the Arts, the New Jersey Department of Community Affairs (Office of State Planning), the New Jersey State League of Municipalities, and Princeton University's School of Architecture. A number of design and planning experts provided technical assistance, including the Centers for Disease Control and Prevention. Contacts are being made with the New Jersey chapter of the American Planning Association and other planning-related entities, a number of other higher education institutions such as Rutgers University and the New Jersey Institute of Technology, and environmental organizations to encourage other partnerships and expand the technical resources available to communities.

The Northeast State Planning Directors Retreat

Created in 1999, the Northeast State Planning Directors Leadership Retreat (NESP) has provided an annual forum for state planning officials from the Northeast States—Maryland to Maine—to come together for a two-day workshop to learn from each other about new initiatives and opportunities in state land use policy. Co-sponsored by RPA and the Lincoln Institute for Land Policy, these annual workshops have evolved into a critical forum for these policymakers to learn the state of the art and share their own successes and failures with their peers. Guest speakers and presenters are brought in for each session, and roundtable discussions provide participants with the opportunity to explore the possibilities for using new techniques and information to better manage land use patterns and control sprawl in their home states.

Beginning in 2002, RPA introduced the healthy communities agenda to this important constituency. The outcomes and process objectives of this initiative are to integrate land use and public health policies at the state government level by educating state officials about the connections between land use and public health and by demonstrating ways that land and environmental policies can promote healthier communities.

The first NESP forum to incorporate these issues was held on April 11 and 12, 2002, in Cambridge, Massachusetts. In addition to RPA and Lincoln Institute staff, participants included

commissioners and directors of state planning and growth management from Vermont, Massachusetts, Delaware, Maryland, Pennsylvania, New York State, Maine, New Jersey, and Connecticut.

At this forum, a roundtable discussion titled "Planning and Designing the Physically Active Community" was moderated by RPA President Robert Yaro. Panelists included Marla Hollander, a program officer with the Robert Wood Johnson Foundation; Reid Ewing, a researcher on public health and land use from Rutgers University; and Marya Morris, a senior research associate at the American Planning Association and the program director for the APA's initiative to promote understanding of healthy communities in the planning profession.

Conclusion

Federal, state, and local governments, together with concerned citizens, can play a strong part in promoting land use policies that address public health directly. Through collaborative efforts with private organizations and others, it is possible to conduct land use planning that promotes healthy habits as a way of both preventing and addressing diseases whose development is partly aided by poor land use policies. The project now nearing completion in New Haven, Connecticut is an example of the way in which communities can improve public health through effective land use planning. The initiatives of the Regional Planning Association in the New York metropolitan area furnish yet another example of the numerous ways that government leaders and governmental activities can bring focus to the issue of creating healthy land use policies.

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Clean Indoor Air: Where, Why, and How

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ABSTRACT

Clean indoor air policies are an effective way to eliminate exposure to secondhand smoke and reduce smoking among youth and adults; they are strongly recommended by the Surgeon General and the Task Force on Community Preventive Services. How these policies are put into effect and at what level of government can make a difference. Legislation that preempts local action prevents communities from enacting more stringent laws or tailoring laws to address community-specific issues. Preemptive state laws also can be a barrier to local enforcement because communities not involved in decision making may be less aware of laws, may have no enforcement mechanism, and thus may be less compliant. Preemption is clearly a tobacco industry strategy to take away local control, usually in exchange for a weak law offering little protection from secondhand smoke. As communities across the country continue to pass stronger local ordinances, eliminating preemptive laws becomes more important. During 2002, Delaware became the first state to repeal clean air preemption. In Iowa, the attorney general's office has been involved in the determination of whether the state clean air law prevents communities from passing more stringent ordinances. And although Minnesota's pioneer Clean Indoor Air Act does not preempt local laws, the debate over preemption there has not ended but instead has taken new forms.

Clean indoor air policies are an effective way to reduce everyone's exposure to secondhand smoke and to reduce smoking among youth and adults. Such policies include smoking bans and restrictions put into effect through laws, regulations, ordinances, and voluntary policies. They are strongly recommended by the Surgeon General[1] and the independent Task Force on Community Preventive Services.[2] The Centers for Disease Control and Prevention's Office on Smoking and Health (OSH) plans to issue a new Surgeon General's report on secondhand smoke, bringing together all the current science on this subject. It's important to remember that the evolving science around the harm of passive smoking underlies the need to protect people from exposure.

The OSH funds all 50 states plus the territories to work on four tobacco control goal areas. Eliminating exposure to secondhand smoke is one of these goals. How clean air policies are put into effect and at what level of government can make a difference.[3] Laws and regulations enacted at the state level benefit public health by implementing widespread standards. At the local level, public debate over ordinances can educate the community about the harm of secondhand smoke and the tactics of the tobacco industry, potentially altering social norms about tobacco use.

This process of intense community involvement and education resulting in environmental change is also important in other public health issues. However, legislation that preempts local

action removes control from communities by preventing them from enacting more stringent laws or tailoring laws to address community-specific issues. Preemptive state laws can be a barrier to local enforcement because communities not involved in the decision-making process may be less aware of the laws, may have no enforcement mechanism, and thus may be less compliant. Preemption is clearly a tobacco industry strategy to take away local control, usually in exchange for a weak state law that offers little protection from secondhand smoke.[4]

One of the *Healthy People 2010* objectives is to eliminate all state laws that preempt stronger local tobacco control laws or ordinances.[5] OSH serves as the data source for this objective, tracking preemption and reporting it through the State System (available on the Center for Disease Control and Prevention's website, www.cdc.gov/tobacco). OSH also encourages state health departments to continually monitor their own local ordinances and, where possible, to track voluntary policies such as in those school systems.

Until quite recently, no state had repealed preemption of its clean air laws. *Healthy People 2010* notes that this objective is moving away from its target; in other words, more states have preemption rather than fewer. In May 2002 on World No-Tobacco Day, the governor of Delaware signed a very strong clean air law that amends an earlier law and clearly does away with preemption in that state.[6] Although Delaware is the first state to repeal a preemption statute on secondhand smoke, health advocates in other states have attempted to repeal preemption statutes and worked to prevent passage. Approaches to repealing preemption laws have involved both the courts and the legislature.

In attempts to change the social systems that encourage smoking, laws and regulations have been very important. Partnerships with the legal community have been critical to creating and enacting policies that regulate the way tobacco products are used, marketed, and sold. The legal community has also been involved in defending health policies against challenges from the tobacco industry.

Currently, five states have formalized relationships between legal centers and the state health department to provide legal assistance to communities involved in tobacco control. This innovative approach began with the Community Action State Team program in Massachusetts, a program that has served as a major resource to municipalities and local boards of health.[7] California, Michigan, Minnesota, and most recently, Maryland have similar programs.

Clean Indoor Air Laws

By mid-2002, the decades-long trend toward more and stronger clean indoor air policies had continued, especially at the local level.[1] During this time, there were also some examples of statewide clean indoor air laws that became more restrictive. As previously indicated, Delaware did away with preemption, becoming the first state to repeal preemption of clean air laws. The new law prohibits smoking in "any indoor enclosed area to which the general public is invited or in which the general public is permitted."[6] The law specifically names restaurants, gaming facilities that are open to the public, any indoor sports arena, lobbies, hallways, and other common areas in apartment buildings, condominiums and other multiple-unit residential facilities in addition to bowling alleys, billiard or pool halls, and retirement facilities. Almost immediately, a move to weaken some provisions was put forward, but was later defeated.

South Dakota also strengthened its clean air law by banning smoking in public places and worksites. Public places, as defined by this law, include restaurants, all elementary and secondary school buildings, all reception areas, and retail stores except those selling liquor or tobacco.[8] A separate bill that would have allowed local units of government to regulate tobacco products did not pass.[9]

Florida has a proposed constitutional amendment on the ballot in November 2002 to strengthen the existing clean air law, but the proposed law remains preemptive.[10] If passed, the new amendment will provide protection from secondhand smoke in "enclosed indoor workplaces," including restaurants. Tobacco shops, stand-alone bars, and

designated hotel guest rooms will be exempted as well as home businesses that do not provide child care, adult care, or health care.

At the local level, Helena, Montana; Barrow, Alaska; Honolulu, Hawaii; Ingham County/ Lansing, Michigan; and Holman Village in Eau Clair County, Wisconsin provide a representative sample of communities that have passed clean air ordinances in the first half of 2002.[11] Ingham County prohibits smoking in worksites; Holman Village prohibits smoking in restaurants. Barrow, Helena, and Honolulu all have 100% smoke-free ordinances covering both workplaces and restaurants.

These communities are now part of the over 1400 local jurisdictions across the United States that have passed regulations to reduce or eliminate exposure to secondhand smoke. By working at the local level, tobacco control health professionals have helped change community norms concerning tobacco use and reduced the cues for smoking.[12]

The Minnesota Experience

Minnesota's Clean Indoor Air Act,[13] while problematic in some respects, is relatively clear in recognizing the authority of local governments to enact strong local indoor air laws. Before allowing public discussion to shift to abstract analysis of the powers of overlapping state and local governments, it is important for advocates to insist on educating lawmakers about the underlying health issue associated with secondhand smoke. Lawmakers, like most other Americans, will usually acknowledge that secondhand smoke can exacerbate health problems for some nonsmokers, but this awareness falls far short of a genuine understanding of the hazard. The true dimensions of the issue can be gauged in different ways. The basic facts bear frequent repetition because many lawmakers have difficulty believing that secondhand smoke represents the third leading preventable cause of death, that no minimum level of exposure is safe, and that this hazard kills 53,000 or more victims annually in the United States,[14] Juxtaposition of this issue with better-known threats can also create a compelling point of reference. No official doubts that crimes of violence cause sufficient societal harm to warrant strong legislation; yet, few of these officials understand that for every American murdered, two die from secondhand smoke.[15]

Perhaps the most reliable way to assess the importance of the secondhand smoke debate is by the response of tobacco manufacturers. Once-secret internal documents now show the industry's intense apprehension of this issue, which industry insiders have called "[t]he most powerful anti-smoking weapon being employed against the industry."[16] These fears, and the ferocity of the industry's opposition, are explained by the potency of the issue. Smoking restrictions do more than protect the health of workers, customers and others exposed to unwanted smoke. They reduce children's exposure to negative role models and re-shape social norms. In the process, they engage the self-interest of the great nonsmoking majority of the citizenry and, among other things, encourage those in smoke-free settings to quit smoking and make it easier for them to avoid relapse. This is why the Tobacco Institute secretly identified workplace smoking bans as "[t]he most effective way to reduce smoking."[17] The magnitude of this effect is stunning, if we accept Philip Morris' confidential calculation that "[i]f smoking were banned in all workplaces…the quitting rate would increase 74% …."[18] With this much at stake for manufacturers, every proposed smoking restriction is guaranteed strong opposition.

The State of the Law in Minnesota

Minnesota's state Clean Indoor Air Act, the first in the nation, was considered bold when adopted in 1975. It did not eliminate smoking in public settings, but merely required creation of "smoking permitted" and "no smoking" areas—and even this requirement was subject to exceptions and limitations.[13] Still, this measured approach was enough, in 1975, to provoke angry reactions, dire predictions that enforcement would require the posting of police officers in every restaurant or office building, and other

breathless arguments familiar to those who advocate today's stronger measures.

Over time, the Act was strengthened and reinforced so that today the Act, its implementing rules, and other complementary provisions effectively prohibit smoking in certain types of venues, including most state government facilities, public schools, hospitals and clinics, public transport, day care centers, and most public sports facilities.

Elsewhere, however, the quarter-century-old paradigm of "smoking" and "non-smoking" areas prevails, with some settings, such as bars, exempt even from this requirement.

Now, as understanding of the medical hazard has grown, so too has interest in strengthening this regulatory approach. In several dozen Minnesota communities, local coalitions of health professionals, advocates, and other community leaders have formed to promote more effective control of secondhand smoke. In some communities, these efforts have focused on education and voluntary changes; in others, the focus has been on proposed new ordinances. Since 2000, four Minnesota communities—Moose Lake (2000); Duluth (2000, 2001); Cloquet (2001); and Olmsted County (2001)—have enacted new local ordinances restricting smoking in restaurants or workplaces generally. In each instance, officials reported that the public debate was the most heated in local memory.

The Push for Preemption

Minnesota's Clean Indoor Air Act is relatively clear in preserving the power of local governments to impose their own smoking restrictions, above and beyond those of state law. In limiting smoking to designated smoking areas, the Act allows businesses to create smoking areas wherever they wish "except in places in which smoking is prohibited…by other law, ordinance or rule."[19] This express recognition of the continuing role of local ordinances would make it difficult to sustain a serious preemption challenge to local ordinances. Any lingering uncertainty on this point appears to have been resolved by a recent Opinion of the Minnesota Attorney General confirming that the Act regulates smoking "while expressly preserving the power of local government to impose more stringent smoking limitations."[20]

Minnesota advocates are watchful for possible efforts by tobacco industry representatives and others to enact new preemptive language at the state level. No serious efforts along this line have yet materialized, perhaps because veteran legislators are reluctant to repeat divisive preemption battles that accompanied enactment of Minnesota's youth access legislation in the 1990s. Nevertheless, many advocates consider a state-level preemption proposal likely as local activity accelerates.

Running through the arguments against ordinance proposals in Minnesota have been a series of variations on the theme of preemption. These are not typically characterized as "preemption" arguments, per se; instead, opponents have simply re-cast these arguments in political, rather than legal, terms. These arguments take several forms:

1. This issue should be left for statewide solution, because local smoking laws create an uneven playing field for local businesses, putting them at a competitive disadvantage in relation to businesses in neighboring communities.
2. Local governments should leave this issue to experts at the state or federal level, because city council members, county commissioners and their staff lack the technical expertise to understand the complex health issues involved.
3. Local officials should leave this issue for solution through the state rulemaking process under Minnesota's Clean Indoor Air Act.

Since 2001, many Minnesota communities have seen a very specific manifestation of these preemption-like arguments. In nearly a dozen municipalities and at least one county—primarily communities where the issue has not yet come under active consideration—opponents have used arguments such as those suggested above to persuade elected officials to adopt a formal standardized resolution, declaring the locality's

determination to "defer" indefinitely to state government to solve the problem of secondhand smoke. When presented to a decision-making body without significant community mobilization or discussion of the issue, this tactic has proven attractive to many local officials, who may be relieved to avoid a contentious issue. This tactic appears to be proliferating and should be anticipated in other states.

Legal Technical Assistance: A Vital Resource

Minnesota differs from most other jurisdictions in another respect, as well: it is one of only a handful of states to offer local officials and tobacco control advocates technical assistance with legal issues such as preemption, consistent with the CDC's *Best Practices for Comprehensive Tobacco Control Programs*. Through its Youth Tobacco Prevention Initiative, the Minnesota Department of Health funds a small legal resource center, the Tobacco Law Project at William Mitchell College of Law in Saint Paul. Modeled after California's Technical Assistance Legal Center and Massachusetts's Tobacco Control Resource Center, the Tobacco Law Project offers free, objective information and assistance in the form of sample ordinances, legislative drafting, legal research and analysis, training, and assistance in responding to objections. Similar programs are in place in Michigan (the Smoke-Free Environments Law Project) and Maryland (the University of Maryland Law School's Legal Resource Center for Tobacco Regulation, Litigation and Advocacy) and are being developed in additional states.

In May, 2002, in an effort to better coordinate their efforts, spark synergies, and identify opportunities for meeting the legal needs arising from other states, the existing legal centers joined with other tobacco legal experts to begin the formation of an effective network for legal technical assistance. Provisionally known as the Tobacco Control Legal Consortium (TCLC), this new network will serve to foster communication and cooperation among attorneys and tobacco control advocates on legal matters related to tobacco control and to coordinate resources for legal guidance. Initial priorities for the Consortium, in addition to developing a more formal organizational structure, will include educating key audiences about the role of legal technical assistance in tobacco control, recruiting additional attorney experts as tobacco control resources, helping other states create new legal resource centers, and perhaps, in certain instances, providing limited "rapid response" assistance. The participants are hopeful that this important new initiative will lead to expanded assistance for advocates and officials nationwide in dealing effectively not only with issues related to secondhand smoke, but with the entire spectrum of legal issues in tobacco control.

The Iowa Experience

By 1997, serious attention was being given in Iowa to passing local ordinances restricting smoking beyond the modest restrictions in state law, which still allowed smoking sections in restaurants and many other public places and workplaces. As "de-normalization" of tobacco use became a more and more prominent goal, supported by a growing number of studies of the adverse health effects of ambient tobacco smoke, the desire to further restrict public smoking was becoming more intense.

Tobacco control advocates in Iowa, however, felt stymied. The state law setting forth the smoking restrictions included what appeared to be a preemption provision. Advocates had trouble galvanizing support in local communities for enacting further smoking restrictions when the locality could be expected to be the target of a legal challenge, a challenge that appeared likely to succeed. The only apparent alternative was to go to the state legislature to try to get the preemption language removed, but the tobacco industry's considerable influence in state legislatures was very well known (which is why local regulation was so attractive in the first place).

The language in the state law regarded as preemptive states: "Enforcement of this chapter

shall be implemented in an equitable manner throughout the state. For the purpose of equitable and uniform implementation, application, and enforcement of state and local laws and regulations, the provisions of this chapter shall supersede any local law or regulation which is inconsistent with or conflicts with the provisions of this chapter."[21]

Although the state law on smoking restrictions was enacted in 1979, the language quoted above had been added to the law in 1990 as part of an otherwise benign-looking set of amendments that required restaurants to have no-smoking areas and that raised the penalty for violations from $10 to $25. The industry was characteristically way ahead of the curve and was probably the source of the quoted provision as part of a strategy for ensuring that future battles over tobacco would be fought in only those arenas where the industry held the greatest advantage, that is, the state legislature.

As of about 1997, Iowa's tobacco control advocates were enjoying virtually no success in getting localities to pass ordinances restricting smoking. Local authorities did not wish to become enmeshed in what looked like a losing legal battle with the tobacco industry, which at the time was known for a scorched-earth approach to litigation that always resulted in victory.

At this point, the Attorney General's Office undertook a legal analysis of the language in question, to examine whether the law included preemption language as many tobacco control advocates believed. In fact, there were sound legal grounds for questioning whether the language in question had the preemptive effect it was thought to have. Iowa has what is called a "home rule" tradition of local control, and anyone arguing that localities have been deprived of their home rule authority has to overcome a strong presumption to the contrary.

Statutory language that is claimed to override local power must do so clearly and forthrightly. An earlier instance of such clarity in the obscenity context involved this language: "No municipality, county or other governmental unit ... shall make any law, ordinance or regulation relating to obscenity." Obviously, the legislature was able to make its intent to preempt unmistakably clear when it so desired.

The Iowa Attorney General's Office ultimately concluded that the law was not preemptive. That legal analysis was shared with tobacco control advocates, city and county attorneys, and legal advisors to localities.

At the same time this legal position was taking shape, public perception (and, undoubtedly, the attitude of judges) was changing. During the nineties, a steady drumbeat of damaging disclosures of tobacco industry misdeeds and the dangers of secondhand smoke increased the desire for effective regulation.

In the wake of the Attorney General's favorable conclusions regarding local powers, some localities began organizing the necessary support for an ordinance in earnest. At that point a state legislator from one of these communities requested an official Opinion of the Attorney General on the preemption issue. In doing so, the legislator highlighted yet another argument for non-preemption that was tucked away in one of the provisions of the state law on smoking prohibitions.

One term of the state statute regulating public smoking provided as follows: Smoking areas may be designated by persons having custody or control of public places, except in places in which smoking is prohibited by the fire marshal or by other law, ordinance, or regulation.[22] This provision clearly contemplates that there might be local ordinances that prohibit smoking in public places in which the state statute permitted smoking. This made it hard to argue that the paragraph requiring uniform implementation, etc. (the supposed preemptive provision) was intended to remove all such power from local authorities.

A formal Opinion of the Attorney General was issued in November of 2000. It supported the view that there was no preemption. Although such an Opinion is not binding on Iowa courts, it is given respectful consideration. Localities were further emboldened by the Opinion. The city of Ames, Iowa passed an ordinance restricting smoking in restaurants. Seven restaurants claiming to be adversely affected by the ordinance

sued to enjoin its enforcement. The source of funding for the suit became an issue, and Philip Morris admitted that it was bankrolling the suit, a disclosure that garnered considerable publicity.

Philip Morris and the restaurants sought a temporary injunction, which was denied by the court. At that point, Iowa City passed an even more restrictive ordinance banning smoking in restaurants. To date, there has been no suit attacking that ordinance.

The district court's ultimate ruling on the Ames ordinance came down in February 2002, and it affirmed local authority to regulate secondhand smoke. In a thorough and carefully crafted ruling, the district court judge found that there was no preemption. That ruling has been appealed by the restaurants, and is currently awaiting consideration by the Iowa Supreme Court. The restaurant's appeal mounts a vigorous attack on the lower court ruling, and the Iowa Supreme Court will now be presented with an opportunity to finally settle the preemption issue.

If the Iowa Supreme Court rules that there is no preemption, it is likely that other communities will pass smoking restrictions. If the Supreme Court rules that there is preemption, at least the issue will be served up to the legislature in the context of two Iowa communities having tried to protect the health of their citizenry, and having been thwarted in that effort by what many would regard as a technicality. Although it is never easy to pass legislation opposed by the tobacco industry, it would be a fairly promising context in which to approach the state legislature.

Lessons Learned by Experience

Legal provisions that may have been promoted by the tobacco industry in an attempt to preempt localities from regulating smoking may not be effective in achieving that goal. After all, an industry effort to quietly slip a preemptive provision into state law is likely to be effective in avoiding controversy only if it is couched in ambiguous code words, leaving many (including legislators) unaware of its disempowering potential. But that same ambiguity may work against it in the courts. A thorough analysis of the overall legal framework may show that the language feared to be preemptive does not have that effect. Furthermore, judges called upon to rule on preemption issues may be reluctant to let ambiguous provisions keep communities from protecting their citizens from the increasingly well-known hazards of secondhand smoke.

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Policy Tools for the Childhood Obesity Epidemic

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ABSTRACT

The rapid increases in childhood and adolescent overweight between 1980 and 1999 can only be explained by environmental factors. Historically, the most effective strategies to address nutritional problems that have caused such widespread disease have been policy-driven environmental changes. To develop effective public policy responses to the obesity epidemic, we must expand the science base linking environmental conditions and policies to health behaviors and conditions; establish effective intersectoral coalitions of stakeholders; and create effective policy at the national and state levels. Although the childhood obesity epidemic is still evolving, this article provides several examples of potentially effective strategic approaches to address it.

The Need for Public Health Policy to Address the Obesity Epidemic

Public health has a long history of addressing important community issues through regulatory and policy mechanisms. Examples of successful public health policy interventions include the near elimination of rickets through supplementation of milk with vitamin D and the reduction in dental caries through fluoridation of our drinking water. A contemporary example of healthy public policy is the reduction in the prevalence (number) of cigarette smokers. Smoking has been reduced through clean indoor air regulation, targeted taxes, and restrictions on access.

Some policies, however, have unintended effects. For example, some guidelines for the construction of new schools contain "acreage standards" that require large plots of land to provide students with sufficient space to play (and park their cars). Unfortunately, the effects of such regulations also tend to ensure that new schools are placed in undeveloped land, at the periphery of the community.[1] As a result, a growing number of students are unable, or choose not, to walk or ride their bikes to school. Forty percent fewer children reported that they walked or rode their bikes to school in 1995 than in 1977.[2]

Effective public policy is now required to address the growing childhood obesity epidemic. Between 1980 and 1999, the prevalence of overweight 6–11year-old children doubled, and the prevalence of overweight 12–19 year-old adolescents tripled. Almost 15% of children and adolescents are now overweight.[3] Multiple changes have occurred with respect to the source, location, and types of food consumption that have likely increased caloric intake. Furthermore, physical activity as part of daily life appears to have declined, and television viewing among children and adolescents has increased. New approaches will be required to address the obesity epidemic. Effective policy tools require further expansion of the science base, the development of effective coalitions, and the commitment of policy makers. We will provide examples and discuss each approach.

Expanding the Science Base

Planet Health, an intervention developed by Dr. Steven Gortmaker and his colleagues,

provides a good illustration of efforts to expand the science base that relates student behavior to school policies and environments. Planet Health is a school-based intervention delivered in poor communities in and around Boston to prevent obesity. The program was developed based on evidence that television viewing is directly related to obesity, either through its influence on dietary intake or through inactivity.[4] Furthermore, randomized clinical trials and school-based interventions have demonstrated that reductions in television time can be a very effective mechanism to reduce the prevalence of childhood and adolescent obesity.

Schools represent a logical mechanism for the delivery of interventions directed at obesity because most youths are in schools. Moreover, schools are a major source of physical activity and dietary intake. Planet Health is an interdisciplinary curriculum in which health promotion materials are incorporated into existing school structure and core curricula such as mathematics, social studies, science, language arts, and physical education. The intervention was aimed at 6th–8th grade students in ten ethnically diverse schools in the Boston metropolitan area. Behavior targets included reduced television time, decreased consumption of high fat and saturated fat food, increased moderate and vigorous activity, and increased consumption of fruits and vegetables. The study demonstrated reduced obesity among females in intervention schools, increased fruit and vegetable intake, and reductions in television viewing time.

Television viewing appears to be a logical target for the prevention of obesity. Not only is there an evidence base that supports reduced television time, but this study and others demonstrate that reductions in television time effectively reduce childhood obesity.[5] More physical education in schools and policies to promote environmental changes that increase play and walking is needed. These proposed policies include issues related to safety, parental involvement such as walking children to school, and opportunities in programs that promote it.

Policy Tools for Community Organizations to Address the Childhood Obesity Epidemic

North Carolina Prevention Partners (NCPP) is a statewide coalition of organizations that are involved in public health issues such as obesity, accidents, and physical activity. Dr. Meg Molloy, executive director of NCPP, has helped to develop a range of policy tools designed to aid community organizations to counter the obesity epidemic. Strategies have included a report card to assess the efforts of groups in prevention as well as efforts to include preventive insurance benefits. A Winners Circle Healthy Dining Program has been developed to identify and promote healthful choices in restaurants, schools, and convenience marts. The partnership has also promoted the development of a school nutrition/physical activity bill through a state legislative committee as well as the development of partnerships with grassroots nutrition and physical activity organizations.

NCPP intends to increase the visibility of prevention by fostering partnerships promoting prevention and influencing policy. The report card of NCPP's efforts to reduce tobacco use and to promote good nutrition and physical activity provides a strategy to increase the visibility of these issues. NCPP's cost estimates indicate that these risk behaviors cost North Carolina approximately $6 billion per year. The partnership has developed information that helps identify what constitutes substantial preventive efforts in nutrition and physical activity. In response to these efforts, a number of health plans have developed a nutrition benefit, such as access to recreational facilities at corporate discounts. In the area of physical activity, 6 out of 12 health care organizations have established access to physical activity facilities.

The Winner's Circle Healthy Dining Program has also been quite successful in creating consistent, credible, and easily recognized nutrition guidance for consumers and participating restaurants. Venues reached by the Winners Circle include school breakfast and lunch programs,

snack and drink machines at schools, work sites, convenience marts, ballparks, and statewide restaurant chains. As part of the North Carolina Healthy Weight in Children and Youth Initiative, the NCPP conducted formative research related to the nutrition and physical activity environment and promoted insurance coverage of overweight, obesity prevention, and treatment. The policies that NCPP is trying to implement are to increase the time per week for youth involved in physical education to 225 minutes a week in high school, to raise the required high school physical education credits from 1 to 2, and to improve the qualifications of physical education teachers. Legislative efforts to promote nutrition policy have focused on schools. The partners are trying to assure that all foods sold in school meet child nutrition program standards, that schools offer a universal free lunch and breakfast, and that all students have access to water in the classroom and in the vending machines in the cafeteria. More details about these programs are available on the NCPP website (www.ncpreventionpartners.org).

Establishing Public Policy

The State of Missouri provides an example of a potentially effective public policy response to the obesity epidemic. Senate Bill 680, written and introduced by Senator Mary Groves Bland, would create a Missouri Council on Obesity Prevention and Management, establish initiatives to help schools create healthy nutrition environments, and establish a resource data bank for information about obesity. Senator Bland developed this bill in response to her observation that Missouri had failed in the fight against the growing obesity epidemic.

All states have an obesity problem. Over half of US adults are either overweight or obese. According to the Behavioral Risk Factor Surveillance System, Missouri ranks 10th in the prevalence of overweight and obesity in the United States. In 1990 an estimated 46% of Missourians were overweight or obese, and the prevalence increased to more than 56% by 2000. Perhaps most alarming was the finding that the prevalence of obesity alone almost doubled between 1990 (11.9%) and 2000 (22.1%). Although the obesity epidemic has spared no sector of society, in Missouri 44% of African American women and 34% of white women are obese. Although the public is generally aware of the obesity problem, a greater priority is warranted. The prevalence of obesity dwarfs that of many other diseases. For instance, nationwide, approximately 800,000–900,000 persons are living with HIV/AIDS, 8 million with cancer, 16 million with diabetes, 22 million with heart disease, and 58 million with serious health risks from obesity. Although these other diseases are very important, the contribution of obesity to other chronic diseases such as heart disease, diabetes, and cancer, as well as its rapidly increasing prevalence, warrants an increased emphasis on prevention and treatment.

Effective prevention and treatment will require both individual and community-wide efforts. The importance of a community approach is indicated by Surgeon General Satcher's comment: "Many people believe that dealing with overweight and obesity is a personal problem. To some degree they are right, but it is also a *community responsibility*. When there are no safe, accessible places for children to play or adults to walk, jog or ride a bike, that is a *community responsibility*. When school lunch rooms or office cafeterias do not provide healthy and appealing food choices, that is a *community responsibility*. When new or expectant mothers are not educated about the benefits of breast-feeding, that is a *community responsibility*. When we do not require daily physical education in our schools, that is a *community responsibility*" [emphasis added].[6]

Promoting primary prevention, access to care, and policies to change the nutrition and physical activity environments provides a socio-ecological approach to obesity. Primary prevention prevents obesity before it becomes a problem. Assurance of access to treatment for those who want to maintain a desirable weight as well as for those who need to lose weight addresses the needs of people with established overweight or obesity. Policies and environmental changes improve

nutrition and physical activity in families and in the community.

Successful implementation of such strategies requires that we address a number of barriers. First, there is a lack of understanding among families and physicians of the significance of obesity as a disease that affects physical and mental health. Second, schools and communities lack access to healthy food options and to safe, convenient places to be physical active. Third, there is a lack of consensus among health care providers about standards of practice for prevention, early and episodic screening, diagnosis, and treatment of obesity. Fourth, the profit motives of food retailers, restaurants, and schools often conflict with the value of creating healthy nutrition environments. And fifth, legislators, employers, and policy makers do not understand the link between obesity and increased health care costs, lower school performance, and the reduced quality of family and community life for these overweight or obese students.

Barriers to implementation of intervention strategies include both a lack of funding and a lack of policy and legislative frameworks to support multidisciplinary approaches to the prevention of obesity. Senate Bill 680 was proposed as a first step in reducing some of these barriers. The Missouri Council on Obesity Prevention and Management to be created by the bill would be comprised of all stakeholders who are affected by the medical and economic consequences of obesity and who have an ability to bring about change. The Council would have two years to develop a report that:

1. Assesses the full extent of the obesity epidemic and the economic burden in Missouri. This assessment would include review of data from the Department of Health and Senior Services, Medicaid, commercial insurers, and employers;
2. Recommends programs, services, and infrastructure required to combat the epidemic at the state and local levels and within both the public and private sectors; and
3. Contains an estimate of the cost of implementing all of the recommendations.

Under Senate Bill 680, the Council must submit the report to the Governor and to the leadership of the House and Senate in 2004. However, to build on the foundation that is currently in place, the bill also puts two strategies in motion. First, the bill enables schools to implement initiatives to create healthy school nutrition environments. A healthy school environment is one in which nutrition and physical activity are taught and supported in the classroom, the cafeteria, and throughout the school. Such an environment provides positive messages that help students develop healthy eating and physical activity habits. It also provides an opportunity for practice of these healthy habits. Second, the bill requires the Department of Health and Senior Services to establish and maintain a resource data bank containing information about obesity and related subjects. This data bank will be accessible to educational and research institutions as well as to members of the general public.

An additional bill introduced in Missouri would require insurers to offer optional coverage for expenses arising from weight reduction counseling services for policyholders who are at least fifty pounds overweight and who have been diagnosed by a physician as having current or potential health problems related to excess weight.

Senate Bill 680 was passed by both houses but died in committee. Senator Bland expects to introduce a similar bill in the future.

Conclusion

The magnitude of the obesity epidemic and its impact on health and health care costs emphasize both the importance of effective strategies to prevent the development of new cases of overweight and the need for effective treatment of those who are already overweight. Although proven community strategies have not yet been developed, reductions in television time appear to be one sound approach supported by a substantial body of data. The NCPP provides an

example of establishing effective coalitions to enhance the visibility of obesity and to encourage major insurance providers to provide coverage of obesity. Finally, initiatives in Missouri illustrate a commitment to legislation that improves nutrition and physical activity and also indicate an emergent political will to accomplish the policy changes necessary to reduce the prevalence of obesity.

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Tobacco Use: The Impact of Prices

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ABSTRACT

Cigarette smoking continues to be a leading cause of death in the United States, imposing substantial measurable costs to society. Smoking killed over 440,000 people in the United States each year during the period 1995–1999.[1] If current smoking trends continue, over 5 million people currently younger than 18 will die prematurely from tobacco-related diseases.[1] Increases in excise taxes have been shown to be effective in reducing smoking among youth. However, the adoption of tax increases in any jurisdiction is susceptible to many challenges. Furthermore, smuggling of tobacco products and sales of tobacco products over the Internet threaten the effectiveness of tobacco tax increases. This article discusses the effectiveness of excise tax increases on prevention and reduction of smoking. It also discusses factors that influence the legislative adoption of such increases. Finally, it examines potential threats to the use of tobacco taxes as a prevention tool.

Estimates show that smoking caused over $150 billion in annual health-related economic loses from 1995 to 1999, a figure that includes an average annual productivity loss of $81.9 billion and medical expenditures in excess of $75.5 billion in 1998.[1] Given the health and economic burden of tobacco, interventions are necessary to curb the epidemic of smoking and tobacco use. The measures that reduce the demand for tobacco products have proven most effective in reducing smoking prevalence, limiting youth initiation, and increasing cessation rates. Some successful measures include increasing prices by such means as imposing higher cigarette taxes and non-price measures such as providing consumer information, banning cigarette advertising and promotion, and mandating warning labels and restrictions on public smoking. Greater public access to nicotine replacement products and other cessation therapies have been shown to have an impact on the demand for cigarettes.[2]

Of all intervention measures related to demand, price has been shown to be the single most effective means of changing tobacco use behavior.[3] A 1985 Philip Morris International internal document states that

> It is clear that in the US, and in most countries in which we operate, tax is becoming a major threat to our existence. Of all the concerns, there is one–taxation–that alarms us the most. While marketing restrictions and public and passive smoking (restrictions) do depress volume, in our experience taxation depresses it much more severely. Our concern for taxation is, therefore, central to our thinking about smoking and health. It has historically been the area to which we have devoted most resources and for the foreseeable future, I think things will stay that way almost everywhere.

Higher cigarette taxes promote cessation among current adult smokers and reduce cigarette consumption by adult smokers who continue the habit, helping these smokers move towards cessation. Estimates imply that a ten percent price

increase reduces overall cigarette consumption in this group by four percent, with approximately half of the impact resulting from reductions in the number of smokers.[3]

Young adults are about twice as price-sensitive as adults. Estimates show that a ten percent price increase reduces overall young adult consumption by eight percent, with approximately half of the impact resulting from reductions in the number of young adult smokers;[3] the probability of daily smoking initiation among young adults would decline by about 10 percent.[6]

Children and adolescents are about three times more sensitive to cigarette price changes than are adults, with estimates indicating that a ten percent price increase eliminates the smoking habit of this group by six to seven percent.[3] Higher taxes are particularly effective in preventing young experimenters from progressing to regular smoking, addiction, and, for many, a premature death caused by tobacco use. Because children are highly price-sensitive and 90 percent of all smokers start as teens, higher taxes can sharply reduce smoking in the long run.

Higher tobacco taxes also generate substantial revenues that can be used to support comprehensive state tobacco control programs. Revenues from tobacco tax increases fund many of the longest running and most effective state tobacco use reduction programs, including those in California and Massachusetts. Such programs lead to significant declines in the public health toll caused by tobacco. For every dollar spent on tobacco control, over three dollars are saved in avoided direct medical costs.[7]

Opponents of tobacco tax increases typically raise four objections. These objections focus on the potential negative effects of an increase on current levels of tobacco tax revenues, the cost to tobacco users in particular, the possible job losses associated with reduced tobacco consumption, and the fact that tobacco products available via the Internet escape the same tax burden. The facts argue against these objections. To date, no decrease in overall cigarette tax revenues has resulted from an imposition of higher cigarette taxes in any state; to the contrary, overall tobacco tax revenues have always increased. While it is possible that job losses may be associated with higher cigarette taxes, these losses are minimal and temporary in nature. Moreover, money not spent on tobacco products due to higher costs is diverted to other parts of the economy, thus creating jobs to offset any tobacco-related job losses. In addition, poor people, the population most adversely impacted by the health consequences of tobacco use, are much more responsive than higher income persons to increases in tobacco taxes—thus they are beneficiaries rather than victims of increased tobacco taxes. In the United States, estimates indicate that smoking in households below median income level is about 70 percent more responsive to price than households above median income level.[4]

The issue of the availability of tobacco products via the Internet is more problematic. Internet sales represent a new and growing challenge for tobacco control and for policy makers. The gains made by limiting access to tobacco products through imposition of higher prices via increasing the federal tax and the various state taxes; efforts to increase access to information about the health effects of tobacco through warning labels; the imposition of advertising and promotion bans; and laws limiting youth access to tobacco products—all can be seriously compromised and undermined if the use of the Internet effectively lowers tobacco prices and increases youth access to tobacco products. The evidence base on this new source of access is limited but growing.[5] However, the available evidence indicates that Internet sales could be a threat if proper policy measures are not put in place to protect the nation's youth by limiting their access.

Arizona's Experience with the Tobacco Tax

Arizona's experience with tobacco taxation as a means of reducing tobacco use offers some valuable lessons. In 1994, a coalition of organizations was successful in putting an initiative on the

ballot to increase the tobacco tax by forty cents per pack. The lead organizations in this coalition were the Arizona Hospital and Healthcare Association, the American Heart Association, the American Lung Association, and the American Cancer Association. The tax revenues derived from an increase were to fund prevention and cessation programs, research, and health care services. The goals included preventing children from starting to smoke. Although tobacco companies in opposition to the tobacco tax increase outspent the coalition during the campaign to pass the initiative, the coalition still won by a small margin.

The fight over how to spend the additional tax revenue, however, had just begun. From the beginning, members of the legislature attempted to divert the money to the general fund or to uses other than health. In addition, liquor and tobacco retailers attempted to defeat provisions mandating effective prevention and cessation advertising messages.

The current recession was the final blow to the development of a successful tobacco control program and to the continuing battle to allocate the tax revenues to the programs to which the revenues should have gone. Many legislators saw the need to divert the revenues from the measure to general budget accounts.

In the spring of 2002, the coalition, frustrated by seeing efforts to divert the increased tobacco revenues to purposes other than health, began planning for another initiative. This additional initiative was an outgrowth of the coalition's recognition that the price of tobacco needs to be increased even more if there is to be a significant reduction in tobacco usage. The coalition also recognized that the public would support the tobacco tax increase. An earlier 1994 initiative had been placed on the ballot through the process of collecting signatures from 200,000 registered voters. The 2002 ballot proposal was a referendum. The legislature had tried to divert the 40-cent 1994 increase to the general fund instead of the voter-approved health care programs.

The coalition was successful in getting the second initiative placed on the November 2002 ballot. Polling information provides some confidence that the initiative will pass.

The Arizona experience provides several lessons to those who want to support initiatives to increase tobacco taxes as a means of reducing tobacco use and to use the proceeds of such taxes for health purposes:

1. Don't reinvent the wheel—consult with supporters of such initiatives in states that have already successfully developed and implemented initiatives. These supporters can provide valuable advice about how to proceed and what pitfalls to avoid.
2. Build a coalition of organizations concerned about children and the public's health.
3. Speak with one voice and make sure that every stakeholder is truly onboard with an initiative.
4. Pay for good polling before starting so that that the wording of a proposal clearly states a supportable message.
5. Prepare for a constant battle. Winning the election is the starting point, not the end.
6. Identify all potential enemies and be prepared to confront their arguments.
7. Develop responses to opponents' claims before they make them. For example:
   a. It will be claimed that the black market resulting from a tobacco tax increase will be huge. Be prepared to point out that such a market has not developed in other states as a result of an increase in a tobacco tax and that the potential problem can be addressed by funding law enforcement to deal with it if the problem arises.
   b. To the claim that Internet sales will grow and people will cross state lines after imposition of an increase in the tobacco tax, point out that such may be the case for some people, but not for the main target group, children.

Nebraska: Another State's Story

Nebraska furnishes another experience associated with imposing increases in a tobacco tax as a means of promoting a decrease in tobacco usage.

Many in the state have been fighting for an increase in the tobacco tax for three years. Finally, in the 2002 legislative session, supporters of increased tobacco taxes were successful in gaining passage of a temporary 30-cent increase on a pack of cigarettes. As a result of this increase, the tax on a pack of cigarettes in Nebraska totals 64 cents. The new increase, however, will be in effect for only two years, at the expiration of which the legislature will have to re-address this issue to make the tax increase permanent.

In both the 2000 and 2001 legislative sessions, a bill providing for a 30-cents-per-pack increase had been introduced in the legislature and in both cases defeated. The looming budgetary crisis that Nebraska was facing during the 2002 session, however, helped provide an additional reason for legislators to pass such a bill.

Evidence of the long-term benefits of cigarette tax increases and the cost of tobacco-related health issues to Medicaid helped in the initial introduction of a bill providing for a 50-cents-per-pack tax increase. In addition, polling data showed that close to 70% of Nebraskans supported an increase in the cigarette tax at this level. Finally, the Governor showed signs of being supportive of such an increase. Historically, the Governor had strongly opposed any tax increase.

As the session continued, more and more support for the tax increase emerged. The bill, however, was in the Revenue Committee of the Nebraska Unicameral, a committee that has not been supportive of tobacco tax increases over the last few years. In the 2001 session, the approach used in the bill had been to fund several different worthy programs with a 30-cent increase. The reasoning of supporters was that distributing the money in this fashion could help form a strong coalition of people from all around the state to support the tax. This approach was not successful. The Revenue Committee did not look favorably toward a bill that raised a tax and earmarked the funds, and therefore the bill was defeated.

In 2002, however, the bill specified that most of the money from the increase would be placed directly in a public health fund established from monies from the tobacco settlements. In addition, the bill specified that a portion of the funds would be allocated to a tobacco prevention fund and to Kids Connection, a health insurance fund for low-income children. Public support for a distribution of this kind was higher than for any other distribution scheme. The Governor later came out with strong support of the increase and the proposed distribution. Supporters of the bill believed that it was the strongest of its kind ever to go before the Revenue Committee.

The Revenue Committee, faced with a need to generate revenue for a dwindling state budget, was forced to come up with a plan to raise state receipts. The committee came out with a proposal that included a 20-cent per pack increase. The supporters of the original bill, however, opposed the committee proposal. The data showed that a 10 percent increase in the price of a pack of cigarettes decreased consumption; however, 20 cents did not reach that 10 percent level. During a very long and difficult debate on the Revenue Committee's version of the bill, supporters introduced an amendment to raise the increase to 30 cents. This amendment was strongly supported by the legislative body; however, some in the leadership of the legislature were hesitant to support a cigarette tax increase at all. Nevertheless, due to such strong support for the 30-cent increase, opponents in the leadership were forced to include a two-year 30-cent increase in a final revenue compromise that was eventually passed by the legislature. The final compromise was not ideal, but it was a start.

The battle to raise cigarette prices in Nebraska has been very difficult. The opposition has come in many forms. In two years, supporters of the existing increase will need to fight the battle again to make the increase permanent. However, by then, the supporters will have strong data to show the benefits of cigarette tax increases from around the nation. Also, the majority will not want to eliminate a source of funds that the public supports so enthusiastically.

Smuggling: A Real Threat to Tobacco Tax Increases?

Despite the benefits to community and fiscal health of tobacco tax increases, the tobacco industry uses the threat of increased crime, particularly through the smuggling of cigarettes, to argue against them.

Smuggling does have a negative impact on society, and not only because organized crime is linked to these smuggling operations. Of even more concern are the long-term public health outcomes and the decreased government revenues to combat tobacco use and addiction. Youth are most dramatically harmed by access to cheaper cigarettes, since they are far more likely to initiate smoking when cigarettes are available at lower costs[6]. In addition, smuggling supports the tobacco habit of adults who would otherwise decide to quit smoking if they had to pay more for cigarettes. Finally, smuggling costs federal and state governments important tax revenues used to fund comprehensive tobacco control programs and to pay for the medical expenses related to tobacco use.

Cigarette smuggling typically falls into one of two categories: the black market and the gray market. Black market smuggling, also known as contraband, Duty Not Paid, and General Trade Sales, is international smuggling to avoid taxes. Within the United States, cigarette smuggling often takes the form of gray market smuggling, the sale of cigarettes that were produced in the United States for export (and therefore subject neither to the $4.50-per-carton Master Settlement Agreement charge nor to federal or state taxes), and then re-imported into the United States for sale at below-market prices.

Three interest groups are the primary beneficiaries of smuggling: addicted smokers, re-importers/smugglers, and the tobacco industry. Addicted smokers are "benefited" by gaining access to cheaper products. Re-importers/smugglers, who may be connected with organized crime networks or may be simply independent small-time operators, benefit because they reap the profits made on the resale of the re-imported products; so long as they resell the cigarettes below their fair market value but above the price paid to the tobacco manufacturer, they make a profit.

Tobacco companies benefit from smuggling for several reasons. First, cheaper cigarettes undercut the price-sensitivity of youth and adults and thus reduce the number of people who quit or never start smoking. Smuggled cigarettes also help addict new generations of smokers. Secondly, smuggled premium brand name cigarettes introduce new smokers and smokers beyond the United States to these premium brands, in conjunction with prominent international advertising campaigns. Thirdly, the threat of smuggling and increased crime is a convenient argument for the industry to make in lobbying against tobacco tax increases.[7] And, finally, since smuggled cigarettes do not harm the profit margin of the manufacturers, who are paid in full for the product when it is originally exported, there is no financial incentive for manufacturers to help stop the smuggling. If anything, confiscation and destruction of contraband cigarettes by law enforcement authorities actually increases demand for replacement cigarettes and therefore the profitability of the industry, especially when coupled with the other benefits bestowed upon the industry by smuggling.

Cigarettes are, in fact, the world's most widely smuggled legal consumer product. It is estimated that 300 to 400 billion cigarettes are smuggled annually,[8] a figure that equates to approximately 5% of all cigarettes manufactured.[9] It is estimated that a third of all legally exported cigarettes are illegally imported to some country.[7]

Industry documents recovered through a lawsuit brought by the State of Minnesota,[10] research conducted by investigative journalists, and other sources of information point to significant industry involvement in the international cigarette smuggling operations.[8] It is alleged that cigarette manufacturers funnel massive quantities of brand-name cigarettes into known smuggling networks. Smuggling is a major part of the industry's marketing strategy, despite denials of responsibility and protestations to the contrary.[8]

In 1999, a former executive of the R.J. Reynolds Tobacco Company was arrested for assisting smugglers on a Mohawk Reservation in upstate New York. Subsequent investigation revealed that the executive was operating under the direction of a company subsidiary. Through this operation, the company was ensuring that its product was reentering Canada to be sold on the Canadian market at reduced prices, a strategy that was so successful that it led to a tax reduction for the company in Canada because so much otherwise taxable sales revenue was lost to the government due to illegal sales. It was estimated that RJR assisted in the sale of over $700 million of cigarettes on the Canadian black market. An RJR subsidiary admitted participation in the scheme and paid fines and forfeitures of $15 million.[9]

Despite tobacco industry claims to the contrary, smuggling is not invariably linked to higher taxes on tobacco.[9] Data on the price of cigarettes and smuggling rates destroy the connection between taxes and increased crime. For example, countries with low cigarette prices (Spain at $1.20 per pack and Italy at $2.07 per pack) have high smuggling rates. And countries with high cigarette prices (Sweden at $4.97 per pack and Norway at $6.27 per pack) have low smuggling rates.[7]

In the United States, despite a relatively well paid and organized law enforcement system, some smuggling occurs, either through organized crime or through the interstate purchase of tobacco products by individuals. While losses to smuggling directed by organized crime are difficult to estimate, it is estimated that approximately $400 million of state tax revenue is lost annually on a national basis due to the interstate purchase of cigarettes by individuals.[11] Research shows that such purchases are mainly confined to communities bordering a state with lower tobacco prices.[11]

The situation in California illustrates the ambiguity in the debate about the fiscal effects of smuggling. Both the tobacco industry and the California Board of Equalization (BOE), the state agency responsible for collecting cigarette taxes, make broad statements—supported by poorly documented evidence—alleging a burgeoning smuggling operation in California. The Brown & Williamson web site states that "with the stimulus of both the higher state tax and the Tobacco Settlement increase of $4.50 per carton, the cigarette smuggling sector is flourishing in California."[12] The BOE estimates that organized and casual smuggling has resulted in a loss of over $80 million of tax revenues each year in California.[11] A preamble to proposed state legislation in 2002 states that untaxed cigarette sales result in a loss of over $270 million in tax revenue, a figure presumably based on other BOE estimates.[13] Researchers at the University of California at San Diego, however, conducted an independent study to develop better estimates of how much revenue was actually being lost to California as a result of the sale of untaxed cigarettes.[11] These researchers found that even after a 50-cent increase in the price of cigarettes from a voter initiative in 1999, only 5.4% of California smokers avoided the new tax, and 70% of smokers continued to buy cigarettes at the most expensive locations.[11] The vast majority (70%) of smokers continue to purchase at convenience stores, liquor stores, drug stores, and supermarkets—locations with the highest prices. Another 23% of smokers purchase cigarettes at discount stores (such as Cigarettes Cheaper or Wal-Mart) that collect the required federal and state taxes.[11]

The researchers estimate that approximately $51 million in tobacco taxes is lost annually in California as a result of the non-taxed purchases of cigarettes—far less than the nearly quarter billion dollar losses estimated by the BOE.[11] Given that California annually collects $751 million in cigarette tax revenue, the losses to untaxed sources are small relative to taxed sales.

The following recommendations would help to curb illegal and untaxed sales in the United States and abroad:

1. Increase interstate cooperation on prices. Neighboring states should be encouraged to work together to increase taxes to diminish the lure of interstate sales to individuals.

2. Prohibit or tax cigarette sales on military bases. The federal government could prohibit the sale of tobacco on military bases, or at least make those sales subject to state excise taxes.
3. Impose strict liability on tobacco manufacturers. Pass laws that would make tobacco manufacturers liable for the retail destiny of their products, including deliveries through smuggling operations. Tobacco companies could be treated similarly to companies that generate hazardous waste. These companies are responsible for their waste products from cradle to grave; they do not lose either responsibility or liability despite the negligence or illegal handling of the wastes by others.
4. Require licensing of tobacco retailers. Licensing helps ensure the ability of law enforcement and tobacco control agencies to track the sale of tobacco products. Since licensing can require a chain of custody in record keeping, it is an excellent tool to identify sales that avoid tax collection.
5. Increase law enforcement if necessary. Because the illegal sale of tobacco products generally occurs in areas with lax law enforcement and a history of contraband sales, law enforcement should be focused and enhanced in areas where illegal tobacco sales are known to occur. An additional reason is that the illegal sale of tobacco products may be a precursor of the sale of other contraband products and may utilize the same smuggling rings.
6. Support international efforts to curb the illegal sales of tobacco products. The World Health Organization (WHO) is negotiating such an international agreement. The United States and other exporting countries should support the agreement.

Cigarette smuggling is an international problem that has its roots in the active participation and active disregard of the phenomenon by a tobacco industry that benefits when smuggling flourishes. However, despite industry claims, tobacco smuggling is not conducted on a large scale in the United States.

Conclusion

Increases in excise taxes are an effective tool in the public health community's efforts to reduce smoking, particularly among youth. The adoption of excise tax increases on tobacco products requires persistence, both in enacting the increase and in ensuring that the revenues are used to protect the public's health. Contrary to the arguments of opponents of such tax increases, the smuggling of tobacco products and the sale of tobacco over the Internet have not yet diminished the efficacy of excise tax increases.

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Protecting Our Vulnerable Food Supply

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ABSTRACT

From farmyard to dinner table, our food supply presents ample opportunity for dangerous microorganisms or their products to thrive and infect or intoxicate human beings, often with harmful and sometimes fatal results. Traditional controls to protect the food supply include, but are not limited to, law and regulation. But law and regulation are only enablers, an underpinning. Most important to protection of the food supply is organizational leadership and commitment at federal, state, and local levels of government to protect the public's health. This article provides examples of such leadership in locales as diverse as Australia, New Zealand, and Genesee County, Michigan. Even when a supportive law is in place and the will and resources to make the law work exist, competing political and economic worldviews are constantly at work to amend the law and thus adversely affect the public's health.

Law and regulation have been used to mitigate risks to the public's health from the food supply through establishment of standards of operation and practice for those who monitor, produce, and sell food. Ultimately, both legal and regulatory decisions are influenced by perceptions of risk, potential benefits, and likely financial costs as well as by the political philosophy of those responsible for making and enforcing the rules. As one moves downward from national through state to local levels of government, one comes increasingly closer to the day-to-day work that translates the written word and intent of law into practice. This is especially the case at the retail level in restaurants, convenience outlets, grocery stores, and supermarkets, which form the transactional interface between most consumers and the food they purchase to eat.

This article provides discussion of four aspects associated with the task of protecting the food supply:

1. the burden of illness from foodborne disease;
2. the roles played by industry, by consumers, and by government in promoting food safety;
3. practical experience derived from operating an effective retail food service inspection and licensing program in a local health department; and
4. the volatility of current law governing food protection.

While this article emphasizes the relationship between American food law and its application at the retail level, it also provides an international perspective by including a discussion of food protection activity in Australia and New Zealand. In all three countries, federal food law provides the backdrop for activity conducted by state and local governmental public health agencies, even though state and local law, interpretation, and regulation tailor work to fit special circumstances.

The Burden of Foodborne Illness

In excess of 200 known diseases are transmitted through food.[1] These diseases include infections, intoxications, and chronic sequelae. Foodborne infectious agents include bacteria, viruses, parasites, and prions. Intoxicants (commonly called food poisonings) include bacteria

toxins, heavy metals, insecticides, and other chemical contaminants. Disease symptoms range from mild gastrointestinal distress to life-threatening neurologic, hepatic, and renal syndromes.[1,2]

Acute symptoms of foodborne disease outbreaks such as diarrhea and vomiting catch public attention. However, evidence points to the growing prevalence of less frequently reported secondary chronic illnesses, including anklyosing spondylitis, arthropathies, and renal, cardiac, neurologic, nutritional, malabsorbtive, and autoimmune disorders.[2,3] Chronic sequelae may occur in two to three percent of foodborne illness cases.[2]

Every day in the United States, roughly 800,000 people experience the symptoms of foodborne illness, 200,000 experience acute illness, 900 require hospitalization, and fourteen die.[3–8] Contaminated food results in one of every 100 hospitalizations and one of every 500 deaths in the United States. Most estimates of cost are based on only a limited number of pathogens; even so, estimated annual costs of medical treatment and lost productivity range from $5.6 to $37.1 billion.[9,10]

Controls for Food Safety

Government regulation of the food industry is centuries old, and it is widely accepted as a means both to protect public health and to maintain public confidence in a food supply that is increasingly more distant from individual consumers.[11] Traditional controls include tort law, criminal and administrative penalties, public scoring or grading, labeling and advisories, consumer education, industry education, and consumer outrage.

Tort law provides a method to compensate for damages, recognizes and protects certain interests, and prevents future harm.[12] Lawsuits resulting from foodborne illness provide important feedback to firms along the food chain, serving as "economic signals to firms to invest more in food safety."[9]

However, remedies through tort liability generally fail to create sufficient feedback to industry to provide the degree of food safety desired by the public.[13,14] Only a small fraction of illness ever results in a lawsuit.[4] More than 80 percent of foodborne illness goes unreported.[4–8] Even when such illness is reported, causation is difficult to prove. The vast majority of foodborne illness never is traced back to its cause. Not only is the market inefficient at rewarding firms for implementing improved safety systems, but also the lack of tort claims contributes to the incomplete information about foodborne illness. Thus, the market provides a perverse economic incentive for firms not to implement improved food safety measures.

An inefficient marketplace is cause for governmental intervention and penalties. The deterrent effects of punitive measures are well understood; however, penalties are also generally perceived as insufficient to achieve the level of safety that consumers prefer. Proving causation is challenging, with many violations escaping detection. In addition, the ultimate goal of any food safety system must be to create a general atmosphere that emphasizes food safety, responsibility, and knowledge among owners, operators, and employees. Punitive measures may not produce such an atmosphere.

Labeling and warning statements or advisories are an inexpensive, less intrusive, and less burdensome alternative to direct control.[15] However, industry generally is opposed to warning labels,[16] and the usefulness of advisory statements on food is limited because of a general expectation that food will be safe. Not long after a California court required a detailed warning statement on unpasteurized milk,[17] the FDA, recognizing such a general expectation, rejected the warning statement as insufficient, promulgating instead regulations prohibiting the interstate sale of raw milk.[18]

Public scoring and grading systems have instant appeal, both as inexpensive means to provide food safety information to consumers and as means to satisfy the public's right to know. In practice, these approaches increase compliance with general sanitation requirements. After all, public knowledge of a poor inspection report

results in lost business and therefore provides a strong economic stimulus to improvement.

Nevertheless, public scoring and grading systems are often opposed by the retail food industry and are difficult to enforce and interpret in a standardized fashion. Such systems also have the potential to corrupt the inspection process. Many of the disadvantages of public grading systems can be avoided through use of programs that reward superior performers. These blue ribbon and gold star programs create an incentive for implementing improved food safety measures, providing some of the same benefits as public grading without all the negative consequences.

Consumer (public) education programs inform consumers about steps they can take to protect themselves from unsafe food handling and reward those businesses that take measures to protect food safety. Consumer education also provides a base of support for government proposals to strengthen food safety law.

Industry education programs inform businesses about foodborne pathogens and the benefits of science-based, preventive risk control systems. Finally, public outrage has been an important factor in the evolution of food safety laws. For example, Upton Sinclair's muckraking,[19] targeted at the meat packing industry in 1906, induced Congressional and Presidential action in the United States as the public became alarmed by revelations in Sinclair's book.

Regulation of Food Safety in Australia

Like the United States, Australia has a federal system of government. Under the Australian constitution, many powers, such as the power to protect public health, belong by implication to the eight state and territorial governments, rather than to the national government.[20]

Australian food law has generally comprised three regulatory elements:

1. an act of a state or territory parliament establishing the principles, the framework and administrative structures, and offenses and penalties for violations of the act;
2. food standards that set down compositional, microbiologic, chemical, labeling, and quality criteria that food is to meet; and
3. food hygiene regulations to ensure that the production, processing, storage, and handling of food does not result in microbiological or chemical contamination.

In 1980, a national Model Food Act was developed with the aim of replacing multiple state and territory food acts with one consistent food law across Australia. However, states and territories adopted this model act to varying degrees and at different times. As a consequence, food law and its application across Australia remained inconsistent.

State and territory governments did agree, however, to adopt the nationally developed Food Standards Code covering compositional and labeling requirements. This code promoted a greater degree of uniformity of requirements among manufacturers, but the lack of consistency in food acts among jurisdictions was mirrored in the application, enforcement, and interpretation of the Code. Administrative arrangements also varied among jurisdictions, especially in relation to the involvement of local government authorities in enforcing the Code and monitoring the industry.

In 1998, there was another call for uniformity. The report of the Food Regulation Review found a "…wide mix of regulatory approaches in Australia which vary from agency to agency and jurisdiction to jurisdiction. The approaches range from mandatory, and sometimes prescriptive, regulations through a variety of co-regulatory and quasi-regulatory arrangements, to voluntary industry-driven schemes and total deregulation."[21]

Following the release of this report, the Prime Minister, all premiers and chief ministers, and the president of the Australian Local Government Association signed the Food Regulation Agreement on November 3, 2000, committing all states and territories to legislate in line with a model food bill to be developed and to adopt the national Food Standards Code without variation. New Zealand agreed to the Food Regulation Agreement through a treaty with Australia.

The Australian New Zealand Food Authority (ANZFA) is responsible for developing food standards for both countries. In parallel with the Food Regulation Review, ANZFA undertook a comprehensive review of food legislation in Australia. This activity included development of a Model Food Bill and extensive revision of the Food Standards Code. The revision of the Food Standards Code extended nationally uniform food safety standards to cover food handling, premises, and equipment as well as the compositional and labeling requirements previously covered by the Code.

The Model Food Bill agreed to by all jurisdictions is in two parts or annexes. Annex A describes various offenses associated with the handling and sale of food, sets forth emergency governmental powers to address public health risks, and imposes the requirement for governments to adopt and enforce the Food Standards Code. Government entities are to enact these provisions without modification. Annex B covers administrative requirements such as food business modifications of operations and monitoring food safety programs. These provisions are to be enacted in a nationally uniform manner. The food legislation is to apply from source to consumption. However, while all persons handling food are required to ensure that it is safe, some requirements, such as those relating to notification, monitoring, and inspection, do not apply to primary production or else apply only in specified circumstances.

The Food Regulation Agreement of the Model Food Bill also establishes a new national process for developing food standards. Previously, the standards were established by a Ministerial Council consisting of the relevant ministers (generally the health ministers) of all jurisdictions. Under the new arrangements, ANZFA will be reconstituted as Food Standards Australia New Zealand, which will serve as the standard setting body. The standards are required to be consistent with policy guidelines established by the Ministerial Council.

The objectives of the reforms are to:

1. maintain public health and safety by ensuring that food for sale is safe and suitable for human consumption;
2. ensure national consistency in the interpretation, administration, and enforcement of food law;
3. provide an appropriate regulatory framework that is the minimum necessary for effectiveness and that operates efficiently by reducing costs to industry, government, and consumers; and
4. ensure that consumers have sufficient information to make informed purchasing decisions.

Translating Law into Action to Improve the Public's Health—A County Perspective

The ultimate goals of a food service sanitation program at the retail level are to ensure a safe food supply and reduce the incidence of foodborne illness. However, law and regulation alone are not enough to accomplish these goals; adequate resources and specific activities designed to monitor compliance are also necessary. In the United States, oversight tasks often fall to governmental public health agencies. The food service sanitation program in Michigan is one example of the status of food protection programs at the state and local levels. Local health departments in Michigan must meet minimum program requirements set by the Michigan Department of Agriculture. Some local departments struggle to meet these requirements, while others exceed them. Financial resources from the state government are inadequate to support the work necessary to meet minimum requirements, and the state has defaulted on a state-local compact to share these costs. It is up to local governing boards and the staff of local health departments to make the program a priority and to fund and run an effective program.

Genesee County, Michigan has foodborne illness rates that are generally lower than state and

national rates,[22] a remarkable accomplishment when one considers that for just about every other health area, Genesee County has disease rates higher than state and national averages. The lower foodborne illness rates may well be due to leadership at both the county health department and its governing board. The commitment of these two entities has resulted in a steady transformation of the health department's food service sanitation program from previous ineffectiveness to current effectiveness.

Building an effective program at a local health department requires the presence of three conditions: adequate resources, a powerful, well-written food law, and the will to succeed.

Fifteen years ago, the Flint Journal, the major local newspaper, ran an unflattering exposé describing the failings of the Genesee County Health Department's food service sanitation program. At the time, the program was not a priority at the health department, and the reporters printed the embarrassing details of nonexistent or outdated inspections and poor inspection quality. This state of affairs was not acceptable to the newly hired department director nor to the department's governing board. In response to the exposé, the health department overhauled the structure of the food service sanitation program. Local funding of the program received a boost by virtue of increases in both the fees charged for food service licenses and the county general fund allocation. The staff's attitude toward and commitment to the program improved. These internal changes had a significant effect on the level of sanitation and food safety in local food service establishments. Today, fifteen years later, Genesee County has a food service sanitation program that is a source of pride.

Local health departments in Michigan have had strong statutory support for their food service sanitation programs. With the adoption of the Food Law of 2000, local health department program activity could be grounded in an up-to-date federal food code.

With these developments as a foundation, the Genesee County Health Department attended to staff, industry, management, and public needs.

Attending to Staff Needs

The Genesee County Health Department took several actions to address the needs of staff assigned to monitor compliance with its food service sanitation program:

1. Sanitarians were converted from generalists to specialists. Those assigned to the food service sanitation program work only in that program, rather than in all other programs. This action facilitated training, improved staff competence, and assured that food service inspections would not be neglected in favor of "customer demanded" services such as septic or well inspections. Some sanitarians within the food program underwent further specialization in the disciplines of plan review, outbreak response, and vending machine food service oversight.
2. The department implemented an intensive, in-house training program for newly hired staff.
3. The department established monthly staff meetings for the food program sanitarians.
4. Sanitarians were encouraged to undertake continuing education.
5. Sanitarians were encouraged to participate in their professional association and to sit on state-sponsored committees. This activity ignited sanitarians' interest, widened their perspective, and improved their knowledge of duties and the quality of their work. It also enhanced their stature with food service operators.
6. The department hired additional sanitarians to optimize the ratio of food service establishments and regulators.
7. Sanitarians received additional and better inspection tools to complete their work properly—for example, inspection software and laptop computers/printers for use in the field were provided to each food program sanitarian.
8. Sanitarians were given full management support to go "by the book," even though that operating procedure meant backlash from an industry that had not been held to state standards in some respects for years.

9. Sanitarians were given full management support to call enforcement hearings where necessary.

Attending to Industry Needs

Fifteen years ago, Genesee County retail operators had limited interaction with the sanitarians who regulated them. License fees were low, while inspection scores were high and based more on appearance and maintenance than food safety. After sanitarian specialization, inspection scores dropped dramatically (though nothing had changed in the restaurants), and license fees increased just as dramatically. Inspection duration went from minutes to hours. Sanitarian visits to establishments went from once a year (or even less than that) to four or five times a year. Sanitarians started asking questions about operational and preparation procedures that restaurant owners and managers had never been asked before. Sanitarians began requiring restaurant owners to install hand washing sinks, to upgrade plumbing, to buy additional hot and cold holding equipment, to install proper sneeze shields on buffet units, to sanitize, to add hot water capacity, to screen doors and windows, to vent cooking equipment properly, and to get rid of common cloth towels for drying hands.

As a result of these changed requirements, many in the food service industry in Genesee County became frustrated and angry with the health department. To help build a more constructive and collaborative relationship between regulators and those regulated, the county health department took steps to open formal communication, including

1. Starting a biannual newsletter to communicate important food safety and departmental information to the industry. Each issue of the newsletter highlights several food service violations that operators had difficulty understanding or found onerous to correct. Policy and code interpretation changes, fee increases, and staff changes were also announced in the newsletter prior to implementation.
2. Helping the food service industry to start a local advisory board.
3. Establishing a program to recognize publicly those operators with the best sanitation records.
4. Creating guidance documents.
5. Offering a monthly class covering basic food service sanitation. Upon request by any food service operator who will guarantee 25 attendees, the department will take the class on the road—even during weekends and evenings.
6. Offering informal training on special sanitation topics upon request of the operator.
7. Offering a professional food service management course using the curriculum developed by the National Restaurant Association.
8. Reaching out to non-English-speaking food service operators by offering copies of the Food Code and guidance documents in addition to signs and stickers and the basic sanitation class in foreign languages.
9. Producing reports that are legible and uniform in their explanations of violations and their tips for correction.
10. Doubling the number of plan review staff.
11. Requiring consistent upgrades and menu reviews of existing establishments as they are sold to new owners.
12. Pursuing enforcement action more consistently and predictably against food service operators who fail to correct critical violations or to improve overall sanitation.
13. Redesigning the fee schedule to provide incentives for operators who maintain good sanitation or who complete food safety education. License fees were halved for operators who achieved a reduced inspection frequency status (two consecutive operational inspections with no critical violations and very few non-critical violations made an establishment eligible for a reduced frequency of inspection). Operations with a certified food service manager on staff received a credit toward their annual license fees, as did operators who sent all of their employees to the health department's basic sanitation class.

These incentives were so well received by the food service industry advisory board that they served to diminish its opposition to fee increases. Most important for the health department, these incentives worked to improve sanitation and to reduce the incidence of foodborne disease.

14. Canvassing local food service operators by use of a customer satisfaction survey and a needs assessment survey.
15. Creating a Hazard Analysis and Critical Control Points (HACCP) trainer position. At no cost to a food service operator, the HACCP trainer consults and works with key kitchen staff to design a food safety (HACCP) system tailored to the particular establishment. Establishments with valid and enduring food safety/HACCP systems are also eligible for a reduced inspection frequency and thus a reduced license fee.

Attending to Management Needs

Fifteen years ago, the Genesee County Health Department acquired its first computer and wrote simple computer programs to track and schedule inspections. Today, each sanitarian, secretary, and supervisor has a computer used to complete every inspection report. Computerization has enabled the collection of enormous amounts of data that are used in three general ways: to monitor sanitarian performance and productivity, to target education and enforcement efforts, and to permit management to monitor key elements of the food service program mandated by the state. The department also attended to management needs by

1. Establishing a disease outbreak investigation team across organizational lines.
2. Developing protocols for responding to foodborne illness outbreaks, including hepatitis A exposure and acute infectious diarrhea occurrences.
3. Working closely with county corporation counsel, the sheriff's department, and the local prosecutor to maximize its use of the enforcement powers available under the law.
4. Beginning a quality assurance program of sanitarians' written work included in the files covering each food service establishment.
5. Beginning a program to standardize the sanitarians' fieldwork (inspections).

Attending to Public Needs

The public is the least educated participant in most food safety systems. Most members of the public are poorly informed about foodborne illness, its different agents, sources, modes of action, and communicability. Likewise, the public is ignorant about conditions in "the back of the house" in the restaurants it frequents, and it is without appreciation for the real risks encountered from food handled within retail establishments. Educating the public about foodborne illness and the risk to food safety is essential if the public is to participate meaningfully in a system to protect its own health. To encourage public participation, the Genesee County Health Department undertook several actions, including

1. Redesigning the listing of its telephone numbers in the local phonebook to make it easy for food service patrons with sanitation or foodborne illness complaints to know which number to call.
2. Establishing a hot-line that is activated in times of emergency to provide the public with timely information.
3. Developing an audio-visual presentation on sanitation basics to train non-professional members of the public who apply for temporary licenses as part of volunteering for food service work in a small town festival or within an athletic booster organization. Such non-professionals engage in large numbers in these temporary food service establishments. Completing a pre-event orientation successfully is a county requirement. Not only does the audio-visual presentation make the inspection at the actual event go more smoothly, but it also reduces greatly the risk to the public's health.

4. Striking an arrangement with the local daily newspaper to run an article written by health department staff on a weekly basis. Approximately three times a year, this article addresses food safety in the home.

Keeping Food Protection in Place—The Political Perspective

Adopting food sanitation law is a political process. What is adopted can also be amended, repealed, or replaced. As with any regulated industry, the food chain at the retail level contains many who believe that inspection programs are too onerous and that compliance places an unfair economic burden on those regulated. Members of the food industry can belong to powerful trade associations and organize themselves for political action. They can translate dissatisfaction with health agencies and regulatory programs into legislative mandates and prohibitions that erode the regulatory framework and the public's health.

Examples of such reactions are the organized opposition that local governments face when attempting to enact laws that ban smoking in restaurants and other public places and local preemption laws adopted under pressure by many state legislatures.

Local health officials should be concerned about industry-sponsored efforts to gain more control over food sanitation requirements, standards, and processes. Such efforts may range from imposing limits on fees, making effective oversight financially impossible, to total preemption of local standard setting and activity. For example, in 2001, Tennessee's Hotel, Food Service Establishment and Public Swimming Pool Inspection Act of 1985 was amended.[23] This act provides that beginning in 2001 and continuing through 2005, the cost for restaurant permit fees will increase, and the percentage of the fees remitted by the state health department to local agencies for performing inspections will increase. Included in the amendment is a provision that requires the Commissioner of Health to make a biennial review of the fees "to determine the appropriateness and amount relative to the overall cost of the program." However, a part of the amendment provides that after June 30, 2004, no local entity may charge a local permit fee. Between July 1, 2001 and June 30, 2004, localities that do charge a fee must reduce the amount in proportion to the increase in the state permit fee.

There should be no quarrel with a statute that provides for increased funding to local health agencies and imposes limits on the amount of fees collected for regulatory purposes. However, any preemption of a local health department's authority under any guise should be reason for concern. The preemption of a local health department through a prohibition of a funding source for local public health activities imposes a burden on that department. At any time that local authority is proscribed by a state legislature, local citizens lose a degree of self-determination over their own futures.

Once local authority is proscribed by a state legislature, it is a long, arduous, and sometimes impossible task to reclaim it. The best way to avoid having to face the possibility is for local health officials to remain informed and active in the legislative and community processes.

Conclusion

Foodborne illness affects many more people than formal reporting systems track. It results in chronic disease and disability in addition to the more commonly recognized infectious diseases. The law has been used as a tool to protect the public's health at the retail level of the food chain where most people purchase the food they eat. Recognizing that approaches to hygiene, labeling, oversight, and information can be standardized across nations and can reduce morbidity and mortality, some federal systems of government such as those in Australia and New Zealand have moved over time to make more uniform the foundation for, and delivery of, their protective systems. Local communities in the United States can take practical and effective steps to engage the management and staff of enforcement agencies and retailers, as well as the general public, in

efforts to improve the quality and safety of food in permanent and temporary food service sites, including restaurants, grocery stores, supermarkets, and convenience stores. The will, resources, and political support to apply the law consistently, appropriately, and without favor is a prerequisite to successful implementation of these steps. Advocacy is necessary at the local and state levels of government to establish, preserve, and expand regulatory and financial support for programs to protect the public's health.

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New Approaches to Safe Drinking Water

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Abstract

Up to half the population of some states in the United States drink water from small systems not regulated by the Safe Drinking Water Act. The quality of the drinking water from these systems is generally unknown and may be suspect. In many jurisdictions, private wells are the primary source of water. In some instances, construction of wells may have met regulatory requirements but may not have adequately prevented disease transmission. Anecdotal information, periodic water-borne outbreaks, and recent well surveys suggest that there are public health concerns associated with these and similar systems. This article provides an assessment of the need for governmental oversight (regulatory and non-regulatory) of drinking water supplies, describes how a "systems-based" approach might be used to evaluate water supply systems and to identify and prevent possible contamination, and presents case studies describing the systems-based approach as well as a comprehensive approach to environmental health that includes drinking water regulation.

Two recent trials suggest that drinking water that meets conventional treatment standards under the Safe Drinking Water Act may cause from 10 to 33 percent of diarrheal illness in certain water systems. Four to 12 percent of all episodes of diarrheal illness may be associated with this "finished" or treated tap water. Up to half the population of some states, 22–30 million people, drink water from small systems not regulated under the Safe Drinking Water Act. The quality of that drinking water is generally unknown and may be suspect. This problem exists as a result of a focus on regulatory compliance rather than on public health implications.

The "systems approach" is a public health-focused procedure that can be used to ensure safe drinking water. This approach evaluates entire systems of water delivery, beginning with the source, continuing to the user, and ending with the disposal of wastewater. This approach also assesses the existence and effectiveness of barriers in the system.

In 2001, the National Center for Environmental Health (NCEH) at the Centers for Disease Control and Prevention (CDC) held two workshops that identified specific concerns associated with small systems not regulated by the Safe Drinking Water Act. The NCEH held these workshops to clarify the role of the CDC in addressing these concerns. The three major areas of concern are inadequate state and local resources, complacent or over-confident consumers, and the lack of technical assistance for state, local, and tribal environmental organizations charged with monitoring water supplies. The CDC plans to continue this work to increase public awareness of the importance of safe drinking water, to provide the technical assistance needed to state, local, and tribal environmental health agencies, and to propose expanding the Safe Drinking Water Act to include the addition of non-regulatory provisions as a means of assisting small systems.

An Example of Using a Team Approach to Conduct Systematic Water Analysis for Supply Assessments

The Norwalk-like Virus (NLV) is considered the major cause of gastroenteritis worldwide. NLVs are transmitted most frequently between humans through ingestion of food or water contaminated with feces in areas of poor environmental sanitation. The NLV may be resistant to some level of chlorinated drinking water. Signs and symptoms include nausea, vomiting, cramps, and diarrhea usually lasting 24–48 hours. Currently, there is no known treatment or vaccine, and humans are the only known "reservoir"—the host in which the virus lives and multiplies so that it can be transmitted to other susceptible persons.

In February 2001, a waterborne outbreak of a Norwalk-like virus at a winter lodge in the Big Horn Mountains of Wyoming provided an opportunity to conduct a systematic assessment of the safety of a water supply. A team of specialists representing multiple state and federal agencies conducted an environmental assessment of the water-associated outbreak to identify the source of etiologic agents, to determine how the agent entered the water system and how it survived, and to isolate the agent from the water and from ill persons.

The suspect sources of the etiologic agent were found to be the sewage from an on-site treatment and disposal system and from an outhouse. The suspect modes of contamination were an increased flow of sewage, previously unused wells placed into service, and the installation of sewage systems in fractured granite. It is suspected that the agent was able to survive in the receiving soils because of the shallow, coarse texture of the soil and the heavy application of sewage. Also, a water treatment barrier was not in place at this facility. The drinking water was not adequately filtered or chemically treated. Once the agent was isolated in human specimens, the investigation attempted to find evidence of the presence of the pathogen in the water system. The team found that seven of the eight source water samples taken were fecal coliform positive. Norwalk-like virus was found in a water sample collected from the primary water supply well. The genetic "fingerprint" of the isolated virus in the water matched the sequence found in the fecal samples collected from six of the lodge guests who were ill. The conclusion was that sewage contaminated a ground water source used for drinking water, causing 230 illnesses in this community.

This situation raised the following regulatory issues:

1. Who has the authority to close an establishment?
2. When can an establishment be closed?
3. Are more frequent facility inspections the solution and/or should the focus of inspections shift from regulation-based to a process that identifies the potential for system failure?
4. Would construction improvement, a permitting process, and oversight be the solution?

Evaluation of the water assessment effort led to the conclusion that the team approach provided better coordination and communication within the state. The Wyoming Department of Health, the Wyoming Department of Agriculture, the Wyoming Department of Environmental Quality, the United States Environmental Protection Agency, and the Centers for Disease Control and Prevention all worked cooperatively to understand the entire outbreak environment and the interaction of system failures that led to human disease. The team approach to assessing water safety and contamination focuses on effective prevention and response programs, requiring application of epidemiologic, laboratory, and environmental services components to closely coordinate activities. Such successful collaboration, applied nationwide, will allow local and state regulatory and public health authorities to prioritize environmental health risk evaluations for potentially high-risk facilities or geographic areas.

A County-level Drinking Water Assessment Program

In Pennsylvania, the Allegheny County Health Department's Drinking Water Program covers 85 public water systems, including 10 surface water treatment plants, 9 groundwater treatment plants, 22 community distribution systems, 32 non-community systems, 1 small community system, 6 non-transient non-community systems, 2 water bottlers, 1 retail water facility, and 2 water vending machines. These systems serve approximately 99% of the county's residents. The surface water plants range in size from 2 million to 16 million gallons per day, and the ground water plants range in size from 3,300 to 25,000 gallons per day.

All drinking water systems in Allegheny County are required to be in compliance with the Safe Drinking Water Act. The systems are permitted by the state and inspected by the Allegheny County Health Department. The inspections include annual comprehensive inspections, sanitary surveys, filter plant performance evaluations, and source water protection. If needed, enforcement of the Pennsylvania Safe Drinking Water Act is done through the Pennsylvania Department of Environmental Protection. State Act 315, the Local Health Administration Law, gives the Director of the Health Department authority to correct any public health hazard. And the Allegheny County Rule and Regulation Article XVI—Environmental Health Civil Penalties—allows the Director to assess a civil penalty of up to $10,000 for a violation of any of the County or State regulations, with an additional $2,500 per day for the continuation of the violations. Another aspect of this regulation is that the monies collected are deposited directly into a restricted account that can be used only to enhance and improve environmental health in Allegheny County. This fund has enabled the Health Department to buy equipment, to hire consultants, and to perform health surveys when needed.

Non-regulatory activities constitute another important part of the Health Department's program. Such activities are of equal or even greater importance than the use of the traditional enforcement tools, for non-regulatory activities use rewards to encourage water systems to improve water safety. For example, the Health Department has developed an awards program for those systems that make extraordinary efforts to enhance water safety. To be a winner of an award, a system must not only be in compliance with the Safe Drinking Water Act, but the system must also have developed other management systems that assure emergency response capabilities, maintenance of valves, and other precautionary activities. As of June 2002, 31 systems had already received certificates of commendation from the Health Department. Announcements of these awards are printed in the local papers and often mentioned on local television and radio newscasts.

Allegheny County also has a Public Drinking Water Advisory Committee, made up of employees in the water industry, including engineers and academicians, to provide a forum for the discussion of regulations, training needs, and any other issues that might be related to improving the drinking water of the county and the relations of the county with the regulated organizations. Because the Safe Drinking Water Act is continually requiring more monitoring of water, more frequent training is an acute need. The county provides operator training, an activity that is much appreciated by the industry. The county is also involved in the Partnership for Safe Water, a voluntary national program that provides a forum for personnel at plants to discuss water quality issues and challenges.

One of the benefits of the comprehensive approach to environmental health taken by Allegheny County, specifically with regard to drinking water, is that the health department was able to make *cryptosporidiosis* reportable as a means of assuring a good surveillance system for this disease. This comprehensive approach also permits better coordination during emergencies or water line breaks, because the drinking water staff communicates routinely with the food safety staff and with inspectors of rooming houses, boarding homes, and nursing homes to ensure that the water to these facilities is on as soon as possible or that

contingency plans to deal with emergencies exist. The comprehensive approach results in improved water source protection because of the county's enforcement of the regulation covering the discharge of toxic chemicals or high levels of bacteria into the waterways and its Pollution Prevention Program. A plumbing program and enforcement of a plumbing regulation help ensure against any cross-connections or backflows from the sewage lines to the water lines during the installation of plumbing. Overall, a comprehensive system approach to environmental health problems, including enforcement and non-regulatory activities, leads to better environmental protection for the residents being served.

Conclusion

The provision of safe drinking water is a basic public health consideration. As the population of the country expands and greater demands for safe drinking water are made, state and local health departments will be challenged to determine if the water supply is adequate in both quality and quantity. Systematic team and comprehensive approaches to water safety are among the tools that can be used by the public health community to address the challenges that lie ahead.

Asthma: The Impact of Policies On Breathing Easier

Mary desVignes-Kendrick, Janice Nolen, Ruth Jones McClendon, Andrew Goodman

ABSTRACT

Asthma's impact on health, quality of life, and the economy is substantial, and asthma rates are increasing. Currently, there is no way to prevent the initial onset of asthma, and there is no cure. However, people who have asthma can and do lead high quality, productive lives if they control their asthma by taking medication and, as appropriate, avoid contact with environmental "triggers." These environmental triggers include cockroaches, dust mites, furry pets, mold, tobacco smoke, and certain chemicals. This article provides an overview of the asthma epidemic in the United States and its impact on communities. It also discusses federal, state, and local obstacles and approaches to asthma control and provides examples of recent state legislation related to asthma and the key factors in their enactment.

Background

Asthma is a chronic inflammatory disorder of the airways that can result in recurrent episodes of wheezing, breathlessness, chest tightness, and nighttime or early morning coughing. Prevalence data from 1980 to 1996 indicate a consistent increase in diagnosed asthma.[1] Asthma prevalence is higher in children than in adults and is slightly higher in African Americans than in the Caucasian population. Approximately five million children have asthma, and the disease is responsible for an estimated 14 million days of missed school each year. African Americans also have significantly higher rates of indicators of severe asthma—for example, unscheduled emergency department visits, hospitalizations, and deaths. Although in some cases asthma can be easily diagnosed, often it is difficult to diagnose and differentiate it from other respiratory illnesses, particularly in infants, young children, and the elderly.

The cost of asthma in the United States was estimated to be $10.7 billion in 1994 and $12.7 billion in 1998.[2] When extrapolated from 1998 figures, costs for the year 2000 were an estimated $13.8 billion. Most of these costs are for preventable emergency department visits and hospitalizations. Although appropriate management of people with asthma should decrease the overall cost of the disease to society, the most important benefit would be the improved health and well being of people with asthma and their families.

Genetics and environment both play a role in the cause of asthma, but, in fact, we understand little about the cause of the disease. Tobacco smoke and dust mites appear to have independent roles in the development of asthma in some people. Still, much more is not understood about the causes of asthma than is understood. More is understood about the cause of asthma attacks or exacerbations in people with asthma than about the cause of the disease itself. It is known, for example, that exposure to dust mite or cockroach allergens and furry or feathered animals can cause attacks in allergic individuals. Exposure to irritants such as tobacco smoke, volatile chemicals, and ozone can also cause attacks. Finally, respiratory infections, exercise, emotions,

and changing weather patterns are known to be common triggers of asthma attacks.

Appropriate medications and avoidance of triggers are the primary means of controlling asthma, an approach that includes dealing with the chronic inflammation by using long-term control medications and using quick relief medications to address the recurrent episodes of airflow limitation.

Proper case management should avert many emergency department visits and hospitalizations as well as much of the anxiety associated with asthma. Given the complexity of the disease, education is the key in case management—education not only for people with asthma, but also for their families and for those providing medical care.

Like many other chronic diseases, asthma can benefit from legislative intervention. This paper will explore national and state legislation related to the disease.

Legislation and Policy to Improve Asthma Management and Control: A National Organization's Perspective

The American Lung Association (the Lung Association) is the nation's oldest voluntary health organization, founded in 1904 to fight tuberculosis. Today, the organization is a leader in the fight against the tobacco industry, air pollution, and asthma. The Lung Association is committed to making changes that will help everyone breathe easier, especially the millions of Americans with asthma. The Lung Association has been involved for decades in advocating legislation, especially at the national level, to provide cleaner air and better health, and efforts are continuing. It is also working to build an infrastructure of state and local advocates for asthma, giving them the skills and the tools to make changes closer to home.

National Legislation

Currently, one federal law and two federal bills relate particularly to asthma. The Clean Air Act is an old war-horse that has been a key tool in the protection of public health. The two bills are Health Tracking, a new initiative that may greatly influence the long-term understanding of asthma, and the Asthma Act, which would strengthen national surveillance and planning and improve opportunities for outreach.

The Clean Air Act

Air pollution, indoors and outdoors, is a well-documented trigger for asthma. Study after study link levels of smog and soot to increased asthma attacks, increased hospitalizations, increased visits to hospital emergency departments, and death. The United States has made great progress in the last thirty years in cleaning the air. The key has been the Clean Air Act and the commitment to enforce it. Historically, the Clean Air Act has been one of the most successful environmental laws since its revision in 1970. However, since 1997, decisions of the Environmental Protection Agency (EPA) and prolonged legal challenges have delayed steps to strengthen protections for human health required under the Act.

On May 30, 2002, the Lung Association and seven other national, regional, and local groups issued a 60-day notice of the intent to sue EPA over its failure to take steps to designate areas as either attaining or failing to attain the national ozone standard adopted in 1997. The groups are committed to ensuring that no more delays prevent the attainment of cleaner air. In addition, the Lung Association is concerned about federal proposals that would weaken the Act, substituting language to allow industries and utilities to trade the right to pollute without having to meet current requirements that provide a baseline of protection. The Lung Association is working to see that the proposed changes provide at least as much reduction in pollution as the current law would provide. The administration has proposed revisions to a section of the law regulating the renovation of current sources of pollution to meet tougher standards. The Lung Association opposes these proposed changes as seriously weakening the Act and stopping several cases in which large utilities were on the verge of settling cases with EPA to reduce pollution.

The Nationwide Health Tracking Act of 2002 (HR 4061/S 2054)

On March 21, 2002, new legislation was introduced in both the United States Senate and the House of Representatives that would establish a Nationwide Health Tracking Network to track the date and location of the occurrence of chronic diseases as well as their potential links to environmental factors. Senators Hillary Rodham Clinton (D-NY), Harry Reid (D-NV), and Edward Kennedy (D-MA) and Representatives Nancy Pelosi (D-CA), Peter King (R-NY), Stephanie Tubbs Jones (D-OH), and Louise Slaughter (D-NY) introduced the legislation.

The legislation follows a demonstration project to show how such a tracking network can be established. The Lung Association has been a supporter, participating in the planning for the demonstration projects. It believes that such a system could be a valuable resource in tracking diseases and perhaps identifying other environmental links to the disease.

The Asthma Act (HR 1682)

Introduced in May 2001 by Representative Nita M. Lowery (D-NY), the Asthma Act expands several national programs on asthma and establishes grants to states and to nonprofit organizations to reach disproportionately affected communities. It authorizes grants to schools to reach children in communities with large numbers of low-income or underserved individuals.

Model State and Local Legislation

The Lung Association has developed both state and local model legislation useful in drafting bills or amendments. Carefully constructed legislation is important to ensure an appropriate public policy approach to asthma. These models also can be used to evaluate proposals developed by policymakers or other organizations. Model bills serve as examples of ideal laws, but legislation must also be drafted to meet the specific needs in a particular area. The Lung Association maintains individual model legislation in each of four areas of focus: program infrastructure, schools, access to health care, and environment.

Model program infrastructure

The State Health Program model sets up a comprehensive state assessment intervention and evaluation program and specifies the components of that program. Components include a surveillance system for collecting and analyzing health outcome and risk factor data, a public education system, and funding sufficient to accomplish these tasks.

A second model provides for the state to formally adopt the goals of *Healthy People 2010* and assigns the responsibility of developing strategies to meet those goals to the state health department. A comprehensive model combines both of these models into one.

Model legislation related to schools

The Lung Association's model legislation for school issues has two basic components: asthma medications and school health systems.

The model for asthma medications establishes a system that permits elementary and secondary school students with asthma to have unobstructed access to their medications, including the right to carry asthma inhalers. It requires parental permission and certification from the health care provider that the child has asthma and can administer the medications alone. It also provides language to protect against liability. The model for school nurses provides for the governing body to adopt the recommended minimum ratio for school nurses to students of 1 to 750. This standard is based on recommendations from the National Association of School Nurses. Comprehensive model legislation combines these two recommendation components into one school program.

Access to health care models

Good asthma management requires having access to health care for the medications, emergency services, and specialized treatment when they are needed. Health care model laws provide ways to improve that access. Although

many medications are available to treat asthma, the necessary specific drugs or combinations of drugs will differ from person to person. The chief purpose of a law designed to provide access to the medications is to prohibit managed care providers, insurance providers, group health care providers, and others from denying or limiting coverage for certain prescription drugs.

Because the person in the midst of a serious asthma attack can be at risk of death, a second model law requires insurance and managed care providers to include provisions for emergency services without restrictions or prior authorization.

The Lung Association has two versions of model laws for specialty care. Both versions require health insurance and managed care providers to cover direct patient access to specialists. One version specifically mandates coverage of treatment by pulmonologists; the other requires coverage of treatment for chronic, potentially life-threatening diseases by all specialists.

Model laws on environmental triggers

Managing asthma requires much more than merely taking medications or seeing the doctor. It requires limiting exposure to triggers in the environment that can exacerbate asthma.

Indoor air in schools can be the source for a wide range of allergens, irritants, and biological contaminants that trigger asthma attacks. The EPA, working with a group of partners that includes the Lung Association, developed a kit providing guidelines for schools in maintaining indoor air quality. The EPA's Indoor Air Quality Tools for Schools kit provides a systematic approach to help schools understand what their indoor air problems are, how to resolve most of the problems and, most importantly, how to prevent those problems from developing further. The model law on the environment requires the governing body to develop comprehensive guidance for indoor air in schools, including use of the Tools for Schools guidelines.

A second model law prohibits smoking indoors in all workplaces. Secondhand smoke not only causes lung cancer and heart disease, but it is also a powerful environmental trigger for asthma attacks. Banning it in public places can provide great protection to people with asthma. The model legislation includes language for phasing in to restaurants, if needed.

More information about any of these model laws is available by visiting the website <www.lungusa.org> or by calling 1-800-LUNGUSA to reach the nearest Lung Association office. In addition, the website <www.lungaction.org> allows users to email or fax policy makers directly on issues that affect lung health.

Legislation and Policy to Improve Asthma Management and Control: A State Legislator's Perspective

A repeated scenario:

In the afternoon of a normal school day, while Mrs. Johnson, the fourth grade teacher, is talking about geography, most of the students' minds are wandering in thought about baseball and Spiderman and how to look more like Brittany Spears. But Mary's mind is sharply focused as she feels her chest tighten, signaling the onset of another asthma attack. She raises her hand and asks to see the school nurse. The teacher nods, and Mary heads down the hall and toward the next building. Gasping for air now, she gets to the nurse and asks for her asthma inhaler, and the nurse goes to get it out of the locked cabinet. When she comes back and puts it in Mary's now shaking hands, Mary finally gets to use the medicine to quell the asthma attack—12 minutes after she knew she needed it. Will it work, or has too much time elapsed for it to be effective? Does the nurse now call for an ambulance to take Mary to the emergency room?

This scene is repeated in Texas and the United States many times. In the spring of 2001, the Texas legislature did something about it.

Asthma in children is a major public health problem. At the Santa Rosa Children's Hospital in San Antonio, asthma attacks are the number one reason for admission, accounting for 60% of all admissions. The Texas legislature has studied the

problem over the last several years. And while public policy makers love to talk about data acquisition, cost benefit analysis, multiple regression analysis, reimbursement rates, pie charts, and Power Point presentations, it is important to remember that at the end of it all, the purpose of all efforts is to help a child who is gasping for air.

The Texas legislature, a conservative body, took several significant steps to help in the fight against asthma in children. These steps came as several threads wove together to create a powerful political movement. One thread was the tight state budget that created the desire to save money on Medicaid. A second was the work done by the Texas State Health Department and the House Public Health Committee on Disease Management. A third was the development of the Asthma Coalition of Texas, a powerful advocacy group.

HB 342, the Disease Management bill, was initiated by Speaker Pete Laney of the House of Representatives in the spring of 2001, when he assigned the House Public Health Committee on Disease Management to evaluate the role and potential of disease management in public health programs serving chronically ill populations. The House Subcommittee on Disease Management, chaired by Ruth Jones McClendon, worked especially hard to bring all stakeholders to the table to address the issue. The group met on several occasions, choosing to focus on asthma in children for several reasons, not the least of which were the facts that over 300,000 children in Texas have asthma and that asthma is an ideal target for disease management.

Several barriers to implementing effective disease management programs existed. First, disease management techniques are very time consuming for health care practitioners, and these techniques are not currently reimbursable under Medicaid or many private health insurance programs. Second, many private physicians believe that these techniques work only in an academic, clinical setting, not in a private medical practice.

The committee concluded that these problems could be addressed by conducting a clinical study through the Texas Department of Health (TDH) and the legislature appropriated $1 million for the study. The law (Texas Government Code 531. 021912) requires the TDH to use preventive disease management techniques that are transferable to private practice and that compare the outcomes with those from using traditional methods of treatment. The study will look at outcomes related to school absenteeism, hospitalization, frequency of asthma symptoms, the impact of asthma on the family, and its economic effects. The data derived from this study will provide a basis for establishing Medicaid and private health insurance reimbursement. The study will also demonstrate techniques that will be effective in a private medical practice setting.

A very specific problem is addressed by Texas Education Code 30.013. Initiated by the Asthma Coalition of Texas at its conference in the fall of 2000, the law focuses on an odd problem that emerges when well meaning public policies clash: the conflict of laws designed to battle illicit drug use with the need for the use of legitimate drugs. As part of the war on drugs, almost every school district in Texas and in the United States has adopted a zero-tolerance drug policy. Children are prohibited from having any drugs, prescription or non-prescription—even aspirin—with them at school or school events. Zero-tolerance policies also specify that a school nurse or another authorized school official must administer all drugs. Such rules are well intended, but they sometimes produce unintended results, as in the suspension of an entire cheerleading squad during a football season for possession of Tylenol—much to the dismay and outrage of avid football fans in the community. In the case of asthma inhalers, however, the rule creates serious danger by separating the child from essential medication at the time it is needed. With 1,100 school districts in Texas, legislation was the only practical way of authorizing an exception. The legislature took appropriate action in creating a small exception to the zero-tolerance drug rule of school districts by authorizing public school students who have physician-prescribed asthma inhalers to carry them in school and to school functions.

The Asthma Coalition of Texas provided support for both bills. This coalition is a broad partnership of members from health care professions, public education, public health, patient advocacy, environmental agencies, insurance providers, and employers. Coalition members provided expert consultation during the development phase of the bills and testimony at committee hearings, wrote letters of support to committee members and helped put the face of Texas citizens on the problem for legislators. In the Texas legislature, four of five bills fail to pass in a typical legislative session, and it normally takes a new initiative six years to gather the requisite support for passage. However, both asthma bills passed in the first session they were introduced, thanks in part to coalition support.

This legislative endeavor taught several lessons for those who want to draft and pass public health bills in the future. First, the effort was started by solid research backed by House leadership. By itself, this is not a guarantee of success; after all, there are hundreds of fine studies in the Texas legislature gathering dust. But another factor was that a balance existed between broad and narrow legislation. The broad bill on disease management takes a comprehensive approach, will help many people over time, and has the potential to save money in the long run. The narrow bill that focused on asthma inhalers at school energized many people and got them much more excited than a disease management bill ever could. It was an issue that everyone could embrace. Parents vented their frustrations, physicians issued warnings, and legislators shook their heads at a problem they could understand and do something about. That bill put a child's face on the asthma issue. Third, the activism of the members of the Asthma Coalition conveyed to legislators that this was a serious problem that affected citizens from all areas of the state. The members of the Asthma Coalition worked with Representative McClendon, the legislative sponsor of the bill, as a team. Sometimes, advocacy groups strike out on their own, diffusing their efforts and often getting counterproductive results, but this coalition acknowledged Representative McClendon's expertise and followed her direction. The members of the group stayed focused, concentrated their efforts, and came away with marvelous results.

Legislation and Policy to Improve Asthma Management and Control: A Local Health Department Perspective

Although the cause of asthma is not clear, and no cure is known, a lot is known about how to manage and control asthma. Unfortunately, there remains a wide gap between what is known and what is done. To help close that gap in New York City (NYC), the NYC Childhood Asthma Initiative, a multi-component program, increases the capacity of schools, day care centers, and other child-serving organizations to address asthma, to work with medical providers to improve asthma care, and to support partnerships to increase awareness, support legislation, and promote improved coordination among community organizations in the battle against asthma. Supplementing this program is legislation in place to support asthma management and control

Legislation to Improve Asthma Management and Control

Three state legislative actions in New York assist the NYC public health department in controlling asthma.

Improving asthma surveillance

First, many recognize that a basic need of any public health program is good data. NYC, as many other cities and states, relies primarily upon hospital discharge data to describe the extent of the asthma problem and to monitor trends. However, many researchers and public health professionals recognized that emergency department data would provide a wealth of additional information that could be used for planning, research, and evaluation. As a result of meetings of the NYC Asthma Partnership with sympathetic legislators, a bill was drafted to include data reflecting emergency department diagnoses of

asthma with the New York State hospital discharge diagnosis reporting system. While one use of this information would be to track asthma and the impact of programs to address it, many other health problems could also be assessed with the addition of data on emergency department diagnosis. It was also recognized that given the existence of a statewide system for collecting hospital discharge diagnoses, the added cost of collecting emergency room data would be small.

To ensure passage of the bill, the NYC Asthma Partnership, an organization comprised of more than 300 members, conducted a major campaign to inform key legislators about the potential benefits of the bill and its minimal associated costs. Although there were many supporters from a wide range of organizations concerned about asthma, some legislators had concerns that the data from emergency departments would be used to unfairly profile doctors or hospitals. Nevertheless, in September 2001, the New York State (NYS) legislature voted overwhelmingly to expand the current hospital discharge diagnosis tracking system to include emergency department diagnoses as well.

Administration of asthma medications at school

As Texas did in 2001, NYS passed legislation in July 1998 requiring school districts to allow children to take asthma medicines during the school day (NY Education Law 916). As a result, NYC school children may carry their medications and self-administer them as needed; if they are unable to self-administer, children may have the medications administered by a school nurse. This legislation is likely to reduce absenteeism due to asthma, as children who might not have attended school with mild respiratory symptoms are now more likely to attend. In addition, children who need medicines prior to exercise can self-administer now, and children who develop symptoms will have ready access to medicines. Furthermore, since a physician's note is required as a condition of a child's taking medicines in school, this bill may result in more children with asthma being assessed by medical providers and appropriately treated.

Reducing environmental tobacco smoke

NYC is in the forefront of the nationwide effort to reduce smoking and the associated environmental tobacco smoke. Recent cigarette tax increases in NYS and in NYC are likely to aid this effort, since the increases are substantial enough to discourage the beginning and continuation of the smoking habit. The NYC excise tax increased in July 2002 from 8 cents to $1.50 per pack; in March 2000, the state excise tax had been increased from 39 cents to $1.11 per pack.

Other Issues Needing Legislation

Several other issues call for legislative or policy change to support local or state asthma control programs:

1. Community health outreach workers. Many programs with community health outreach workers have had great success in helping families control asthma. The outreach workers are recruited from the communities where service is provided and are trained to provide basic asthma education, to assist with access to medical care, and to assess the home environment. Legislation and policy to ensure a funding stream to support this valuable but currently under-funded service are highly desirable.
2. Comprehensive environmental controls. Legislation or policies to reduce both indoor and outdoor air pollution exposure would offer relief for people with asthma. Legislation to impose environmental controls on sources of air pollution could improve the quality of life of thousands of children.

Conclusion

Reducing exposure to environmental triggers that can lead to asthma exacerbations, assuring access to medical care for all, improving access to medications that control asthma, and providing health information and education to people with asthma and their families have been shown to improve the health and quality of life of people

with asthma. Legislation can play an important role in assuring that each of these is available to all people with asthma.

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Fluoridation at Fifty: What Have We Learned?

Edwin "Ted" Pratt, Jr., Raymond D. Rawson, Mark Rubin

ABSTRACT

The question posed by the title of this article encompasses more than just the law and science applied to fluoridation. A review of the history and present status of fluoridation policy development and implementation makes it quickly apparent that the lessons learned are applicable to a wide range of public health policy and that the public health community needs to be very concerned about the status and trends of legal precedent. Indeed, in the context of recent U. S. Supreme Court decisions, the need for a comprehensive and coordinated effort to educate the public, legislators, and jurists about the safety and efficacy of community water fluoridation is clear. Two fundamental issues are at the core of this article: (1) the use of science in formulating and defending public health policy, and (2) how to connect scientific fact with the legal process in connection with the actual circumstances regarding a community's health status. The opening section of this article presents an analysis of fluoridation's great success in preventing dental caries over the past 50 years, along with a discussion of current data scientifically demonstrating that fluoride is safe when properly utilized. A second section provides an overview of one state's legislative experience in mandating fluoridation and the political challenges encountered. A final section discusses the legal issues associated with fluoridation, including the bases of legal challenges to public laws mandating it.

Does it work? Comparison of four studies (NH1, 1971–1973; NIDR, 1979–1980; NIDR, 1986–1987; and NH III, 1988–1994) shows both an absolute decline in total number of dental caries in all age groups from 5 to 17 years from 1973 to 1994 as well as a dramatic "flattening out" of the increase from age 5 to age 17. These data demonstrate not only a reduction in dental caries in 17-year-olds by more than 50%, but also a reduction in the rate of increase among children 5 to 17. Current data indicate that 58% of these children are caries-free, 20% have low caries, and 20 % have high caries.

The national data on the status and trends of children's oral health indicate significant improvement since the introduction of drinking water fluoridation over 50 years ago. In addition, specific studies support the positive effects of this public health policy. While there are certainly deviations from the standard of randomized, controlled, prospective, double-blinded clinical trials used—for example, by the Food and Drug Administration to test new drugs—the studies are sufficiently rigorous to provide effective evidence of fluoride's efficacy in preventing dental caries. More specific studies performed by private industry regarding fluoride toothpaste provide more evidence that fluoride works—800 controlled trials indicated a 15-40% decrease in caries. Further, studies of the effect of discontinuing fluoride use almost always show an increase in tooth decay. Recent evaluations of the cost–effectiveness of fluoridation demonstrate an annual per-person cost savings to communities of $15.95 to $18.62 attributable to obviation of dental treatment.

When fluoridation of public drinking water supplies began in the late 1940s, only a few other readily available sources of fluoride for the protection of teeth existed. Since then, a myriad of products offering sources of fluoride have become available—even food processed with fluoridated water is a source. Such products are certainly of great benefit to the 42% of the United States population without the protection of fluoridated drinking water; they also help to provide fluoride to those who choose to use a significant amount of bottled water, most of which is un-fluoridated.

While the increased possibility of enamel fluorosis is a risk associated with higher than optimal amounts of fluoride ingested during early childhood, that risk is very low; in the majority of such cases, fluorosis is not even apparent to the affected individual or casual observer. Those seeking guidance regarding the use of fluoridated products for themselves or their children should seek the advice of a dentist.

The evidence and history of fluoridation indicate that, in general, it is both an effective and a safe method of reducing dental caries. Nevertheless, in a community where fluoridation is proposed, members of the public will always raise questions about that safety. Proponents of implementing this sound public health policy must work hard to present all the strong scientific evidence with all appropriate caveats. Such public education must take place over an extended period of time and feature an emphasis that, in true science, research is never finished—there is always more to learn.

Fluoridation from a Legislative Point of View

The development, introduction, and eventual passage of legislation regarding fluoridation in the Nevada legislature can serve as an example of the political challenges associated with the issue. The primary challenges for advocates of fluoridation of public drinking water supplies were threefold:

1. To educate the public, starting with key constituencies, regarding the benefits of fluoridation;
2. To form coalitions among these constituencies to educate and influence policy makers; and
3. To develop a coordinated strategy to effect policy implementation through appropriate legislation or other actions by governing bodies.

Taking this course of action in Nevada led to the adoption of a bill that provided for fluoridation of drinking water in Nevada.

Initially, the prospects for enacting state legislation providing for fluoridation in Nevada seemed poor. However, the need in the state was clear, and the success of fluoridation in improving oral health elsewhere in the country and its broad, population-based nature made fluoridation legislation a good choice for enactment at the state level. However, before any bill concerning fluoridation could be introduced, it was necessary to do a great deal of work to educate the public about the scientific evidence regarding the effectiveness and safety of fluoride so that key constituencies could be mobilized to support the bill as it was presented and moved through the legislative process.

An important early educational activity was to ensure that dentists were fully aware of the public health issues concerning fluoridation of drinking water. Dentists certainly understood the benefits of fluoride for their individual patients, and they were well trained in the practice of treating oral health problems on a case-by-case basis. However, few had a good understanding of the broader public health concerns of access to care and the impact of poor oral health on early childhood development; an understandable tension existed between the concerns of private dental practice and the broader concerns of public health practice. After all, the application of science to the development of public policy can often run afoul of the exigencies of accepted practice—medical, dental, commercial, or otherwise.

Other constituencies were enlisted in support of educating the public about the benefits and safety of fluoride and the need to let science and fact drive development of policy. The public needed to be aware of the extent of dental disease and the correlation of dental health to overall health. Legislators needed to be informed and encouraged to follow the science and not to fear engaging the arguments against fluoridation.

The costs associated with the lack of fluoridation also needed clear articulation. Millions of children were without the benefits of fluoride. Disease management was grossly inadequate, and remediation of dental disease was very costly. A large volume of junk science and folklore existed within a frightened and tentative population. It was necessary to emphasize that fluoridation has an 80:1 benefit-to-cost ratio and that 80% of tooth decay existed in 25% of the population—mostly children. Existing oral health programs were failing to address the problem successfully—50% of first graders in Nevada and 80% of 17-year-olds had caries.

Finally, common sense dictated that leadership of the initiative needed to focus on practical politics within the legislature. Getting the legislation passed required effective activity within the legislature, coordinated with bringing public opinion to bear. A change in rules allowed the same bill to be introduced into both houses simultaneously, providing an opportunity to move the legislation forward more rapidly. After the actual bill was drafted and hearings were set, the coalition worked closely with the press, providing a significant list of prominent supporting speakers from Nevada and arranging for concise statements from national experts. Commitments of support were obtained from legislators, and votes were carefully counted before the bill was brought to a vote in each chamber.

The success in getting a statewide fluoridation bill adopted in Nevada was built on a combination of grass-roots education, effective presentation of the science and facts, and careful political craftsmanship. While there are certainly many unique activity-influencing considerations in Nevada, the basic strategy and tactics used are certainly a sound basis for similar efforts in other states.

Legal Issues Associated with Fluoridation

Compared with other public health measures, community water fluoridation has been subject to more than its fair share of legal challenges in the courts. Accordingly, fluoridation initiatives should undergo a comprehensive legal analysis by municipal town counsel prior to a vote. Even when this review is well done and the policy is widely supported by the public, the policy may encounter a legal challenge. Among the early challenges to fluoridation, opponents charged that mandatory fluoridation is

1. an abuse of existing municipal authority or else an action lacking authority;
2. a violation of the Equal Protection and Due Process Clauses of the 14th Amendment to the United States Constitution;
3. unreasonable, as in unnecessary, wasteful, or unsafe, with viable alternatives available;
4. in violation of established health laws such as federal laws controlling dispensing of drugs;
5. a forced or compulsory medication; and
6. a violation of individual rights to privacy and liberty.

As a result of these early challenges, fluoridation has been thoroughly tested in the court system of the United States and found to be a proper means of furthering public health and welfare. No court of last resort at either the state or federal level has ever determined fluoridation to be unlawful. Fluoridation has also been clearly held not to be an unconstitutional invasion of religious freedom or other individual rights guaranteed by the 5th and 14th Amendments to the United States Constitution.

Nonetheless, when fluoridation is proposed for another drinking water supply, legal challenges are often raised. In addition, new challenges to existing programs are continually brought forward. To date,

all these legal battles have been won, but the battles are becoming more difficult. The tactics and claims of fluoridation's opponents are becoming more sophisticated, drawing as they do on years of legal precedent and innovative use of recent advances in science and technology. As is usually the case in public health policy, the promoters of fluoridation are nowhere nearly as well coordinated as the very much smaller number of detractors, with the promoters often working in a relative vacuum as they strive to implement or defend a fluoridation program in their communities over the opposition of a coordinated, now international network of anti-fluoridation activists.

Essentially, the opponents of fluoridation have been on an accelerated learning curve, developing blueprints and tactics from existing case law and evolving evermore sophisticated legal theories by mining previous decisions for sources of procedural, equal protection, and due process challenges. In addition, direct actions—or at least threats—against policy makers are increasing, including threats of suits, allegations of personal liability, general efforts at intimidation, and ethics charges.

What could help to effectively resist the growing sophistication and complexity of legal challenges is a more coordinated and informed defense. Rather then having each defending counsel learn from the ground up in isolation, defenders of fluoridation need access to some form of central repository of supporting resources to be developed. The resources that would be included in such a repository are (1) a Fluoridation 101 course incorporating scientific facts and studies of the issue; (2) a legal primer that includes relevant precedents; (3) guidance on qualification and exclusion of expert witnesses; (4) a resource for expert testimony or depositions; (5) guidance on discovery and admission of evidence; and (6) links to a wide range of supporting data from the American Dental Association, the Centers for Disease Control and Prevention, peer reviewed journals, etc. Such a repository could then be linked to interactive, Web-based resources for information sharing and mutual assistance among public health practitioners and their lawyers as they strive to protect and expand fluoridation of public drinking water supplies.

Concluding Comments

The sobering conclusions of this article are that yes, fluoridation programs are still being put in place, but despite the clearly documented success of existing programs and the great need for extending their benefits to the 34% of the nation's population who can be protected and are not on private wells, neither the public nor the court system properly utilizes science to enlighten decisions regarding fluoridation. It is important to protect against a possible trumping of content by form in expert testimony regarding scientific evidence, whereby equal status may be given to experts who represent views not held by the vast number of their peers. Data of a low quality by modern standards of scientific research may well be presented on a par with data obtained by the most rigorous methods and subject to full peer review. Judges and juries, usually having little formal or professional training in scientific methodology, often are unable to accurately weight the validity of competing claims made before them in the name of science. (Ironically, in the fifty years since fluoridation was introduced, the average American has achieved a significantly higher level of education and has far greater access to information.)

In addition, public health's visibility has now receded from the public's eye, which has turned toward medicine and other personal health care practices. The role of population-based policies designed to prevent illness and injury is now poorly understood, whereas in the decades leading up to and largely including the 1950s, the science and practice of public health was held in very high regard, as its great success in improving the nation's quality of life was self-evident. Dramatic advances in scientific knowledge and capability over the last fifty years have failed to make substantial headway in resolving many of humanity's abiding problems, often raising as many new questions as they answer old ones. The result has been to lead many to overlook the

power and success of the scientific method and to view science as just another belief structure. Those who use scientific methods have too easily assumed that their validity is widely understood and accepted.

This unfortunate situation must not cause inaction among scientists. Careful education of key members of the community in the science and facts regarding a public health policy and construction of coalitions to support action can harness the day-to-day political processes of a legislature. The same is true of the legal process. If courts are to better define the meaning of an expert witness and to appreciate and utilize data presented in trials, lawyers must be better educated and supported. The scientific and legal basis for defending and enhancing sound public health policies such as the fluoridation of public drinking water supplies must be nurtured and made accessible to those who develop and defend such policies. Just as in scientific inquiry, where few things can be known with absolute certainty and where experiment and discovery are a continuous process, few arguments about policy are ever settled in an open, democratic society—only temporary accommodations are reached as the ebb and flow of opinion continually roil the body politic. It is not just liberty that requires eternal vigilance, as Thomas Jefferson remarked, but also the effective application of science and law to the development of public policy.

Childhood Immunization: Laws That Work

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ABSTRACT

In the United States, many vaccine-preventable disease rates are at an all-time low. Low disease rates have been achieved through high rates of immunization coverage. Vaccination requirements for school and child care attendance have been recommended by the independent Task Force on Community Preventive Services based on systematic review of immunization interventions. These requirements have been determined to be effective in reducing vaccine-preventable disease and improving immunization coverage rates in all at-risk populations. At the same time, complacency, increasing vaccine costs, vaccine shortages, and the potential risks associated with vaccinations pose challenges to immunization requirements. Some states offer not only medical and religious exemptions to immunization requirements, but also philosophical exemptions for parents who choose not to immunize their children. Policy makers must balance the need to provide individual choice with the need to protect children's health.

Vaccines are among the 20th Century's most successful and cost-effective public health tools for preventing disease and death. Not long ago, diseases such as polio, measles, pertussis, diphtheria, and *Haemophilus influenzae* type b (known as Hib) were commonplace. Today, cases of most vaccine-preventable diseases are at or near all-time lows, and childhood immunization rates have never been higher. In less than a decade, the use of Hib conjugate vaccines nearly eliminated Hib invasive disease among children. During the course of the century, we have eradicated smallpox worldwide and, as of 1991, have eliminated wild polio virus from the Western Hemisphere.

School laws requiring immunizations are effective in ensuring that high numbers of children are immunized. School laws are particularly effective for several reasons: (1) school laws are generally accepted among communities, (2) immunization of children becomes a priority, (3) physicians support school laws, and (4) school laws harness extra resources for immunization.

History, Impact, Current Status, and Enforcement of Compulsory Vaccination

HISTORY

Compulsory vaccination as a means of controlling disease has a long history in the United States, nearly as long as the use of vaccination. In 1809, Massachusetts passed a law requiring the population to be vaccinated against smallpox. In 1827, the school committee of the city of Boston ordered teachers to require all children entering the public schools to give evidence of vaccination, and in 1855, Massachusetts became the first state to enact a compulsory school vaccination law.[1] During the latter half of the 19th Century, many more states passed similar laws. Enactment of school immunization requirements in general accompanied enactment of compulsory school attendance requirements, as it was recognized that bringing large numbers of children together in schools would facilitate the spread of smallpox. By the beginning of the 20th Century, nearly half of the

states had requirements for children to be vaccinated before entering school.

Statutory immunization requirements have been challenged but repeatedly upheld. In 1905, the U.S. Supreme Court affirmed the right of states to pass and enforce compulsory immunization statutes for the population at large, and in 1922, the U.S. Supreme Court upheld the constitutionality of school immunization requirements.

Impact

In the late 1960s, efforts were undertaken to eradicate measles from the United States and it was recognized that transmission in schools was a significant problem. In the early 1970s, it was demonstrated that states that had school immunization laws for measles vaccine had measles incidence rates 40–51% lower than states without such laws. In 1976 and 1977, measles outbreaks in Alaska and Los Angeles led health officials to strictly enforce the existing requirements. Advance notice was given that the laws were to be enforced, and major efforts were made to ensure that vaccination could be easily obtained. In Alaska, on the announced day of enforcement, 7,418 of 89,109 (8.3%) students failed to provide proof of vaccination and were excluded from school. One month later, fewer than 51 students were still excluded. No further cases of measles occurred. In Los Angeles, approximately 50,000 of 1.4 million students (<4%) were excluded; most were back in school within a few days, and the number of measles cases dropped precipitously. These experiences demonstrated that mandatory immunization could be enforced and that it was effective.[2]

In 1977, a Childhood Immunization Initiative was launched to try to reverse gradually declining immunization rates and the continuing epidemics of measles. Since many vaccine-preventable diseases were primarily being transmitted in schools, a major effort was made to review the immunization status of school children and to immunize those in need. Over a two-year period, more than 28 million records were reviewed and millions of doses of vaccine administered. As a result, measles incidence declined and immunization levels in school children rose dramatically. Major emphasis was placed on enactment and enforcement of school immunization requirements, with the result that 30 states formally changed their laws or regulations in the direction of increasing comprehensiveness and more rigorous enforcement. By the 1980–81 school year, all 50 states had laws covering first entrants to school.

In 1977 and 1978, the incidence rate of measles in six states strictly enforcing school immunization requirements was 50% to 90% lower than the rates in the rest of the country. A 1981 study found that the ten states with the lowest measles incidence rates were significantly more likely to have laws covering the entire school population and to be strictly enforcing the laws than were the thirteen states with the highest measles incidence rates. The incidence of mumps in New Jersey children covered by a school law was lower than in children not so covered. Day-care center requirements for *Haemophilus influenzae* type b (Hib) vaccination in New York resulted in declines in Hib incidence among child care attendees that were greater than in the state as a whole. Finally, a study of 796 colleges found that those with state-mandated measles immunization entry requirements were 70% less likely to have a measles outbreak than colleges in states without such requirements.

More recent data concerning the impact of school immunization requirements on immunization coverage come from California, which enacted a requirement that, as of the 1999–2000 school year, all 7th grade students had to provide evidence of immunization against hepatitis B. A survey of 5th–6th graders in San Diego in April–June 1998 showed that only 15.8% had received 3 doses of hepatitis B vaccine. By October 1999, 68.5% of 7th graders had been immunized.[3] Statewide data indicated that in October 1999, 70.6% of 7th graders had received hepatitis B vaccine, but by February–April of 2000, coverage in 7th graders was 89.9 %.[4]

Since the 1981–82 school year, 95% or more of children entering school have documented

immunization against DTP, poliomyelitis, measles, mumps, and rubella. School immunization requirements have not only been highly successful in reducing the incidence of disease but also in improving immunization levels in school children. Unfortunately, levels in preschool children have not been so high, as manifested by the resurgence of measles that occurred from 1989–1991, primarily affecting unimmunized preschool-aged children. Immunization rates in preschool-aged children have been raised to their currently high levels as a result of major efforts (and major infusions of resources) directed at this population during the past ten years.

The Task Force for Community Preventive Services is an independent body carrying out evidence-based reviews of the literature to assess the strength of evidence that preventive interventions directed to populations are effective. One of the seventeen interventions reviewed for vaccine-preventable diseases was mandatory immunization requirements. The Task Force found that sufficient evidence existed to demonstrate the effectiveness of these requirements in increasing immunization coverage and reducing disease incidence, and thus the Task Force recommended their use.[5]

Current Status

As of the 2001–2002 school year, all 50 states, the District of Columbia, and Puerto Rico have school entry requirements. In all states, the requirements cover all grades from kindergarten through 12th grade (three states require only new entrants to show proof of immunization).[6] In all states, the requirements cover day care centers, and in 48 states, the requirements cover Head Start programs. Thirty-two states have some requirements for college entrance. Some of the laws specify the exact vaccines required (and the numbers of doses of each), whereas others authorize the state health officer (or public health board) to designate which vaccines (and doses) will be required, often after a public rule-making process.

In all 50 states, the requirements cover diphtheria, tetanus, polio, measles, and rubella vaccines; 47 states require vaccination for mumps, 44 for pertussis, and 41 for hepatitis B. Forty-nine states require a second dose of measles vaccine, 21 require varicella vaccine, and 6 require hepatitis A vaccine. All 50 states require Hib vaccine for day care attendance and all but Idaho and West Virginia require Hib vaccine for Head Start.

Enforcement and Exemption

The general experience of allowing children to enter school without complete immunization and then following up to try to monitor and ensure that they have been immunized has proven to be a much greater burden on the school system than requiring children to be immunized before they enter school ("No shots, No School").

Some people have medical conditions that increase the risk of adverse effects and should not receive vaccines. Recognizing this fact, all state immunization laws provide for exemptions for persons with contraindicating conditions. In addition, the religious beliefs of some people are in opposition to vaccination, and others are opposed to immunization on other (philosophic) grounds. Further, some persons are not opposed to all vaccines but oppose the concept of mandatory vaccination or mandates for specific vaccines. In the latter case, some may feel they (or their children) are not at risk for a particular disease or that, if contracted, the disease is not that severe. If the disease in question is uncommon (as is the case in the United States today for most vaccine-preventable diseases), these individuals might not be willing to undertake any level of risk of adverse effect.

Forty-eight states currently allow religious exemptions, and sixteen permit philosophical exemptions. Additionally, Arizona and Missouri allow philosophical exemptions in some settings. The criteria used for allowing these exemptions vary greatly. Some states require membership in a recognized religion, whereas others merely require an affirmation of religious (or philosophical) opposition. All 50 states have provisions for excluding noncompliant students from K–12; 47

states have exclusion clauses for day-care settings, and 32 have exclusion clauses for colleges. A 1998 study found that, in 32 of the 48 states with religious or philosophic exemptions, no request for an exemption had ever been denied.

Nationwide, in the 1997–1998 school year, fewer than one percent of entering students had any kind of exemption from immunization laws, but seven states had more than 1%, with exemptions the highest for Michigan, with 2.3%. There are local areas in many states where religious or philosophical exemptions are claimed by a significant proportion of students. For example, in California in 1995, 84% of schools had fewer than 1% of students with exemptions, but 4% of schools had 5% or more students with exemptions. There is some indication that some parents claimed exemptions because it was easier to do so than to go to the effort of finding an immunization record. It should not be easier to get an exemption than it is to get immunized.

Rota et al. studied the processes required to obtain religious and philosophical exemptions to school immunization laws and found that there was an inverse correlation between the complexity of the exemption process and the proportion of exemptions filed.[8] None of 19 states with the highest level of complexity in gaining exemptions had 1% or more students exempted, compared with 5 of the 15 states with the simplest procedure. In these latter states, it often required less effort to claim a nonmedical exemption than it did to fulfill the immunization requirement.

Daniel Salmon, conducting a study of religious and philosophical exemptions to immunization laws, found that in the period 1985–1992, persons with such exemptions had 35 times higher risk of contracting measles than did vaccinated persons. In addition, persons living in communities with increased numbers of exempted persons were at increased risk of contracting measles.[7]

In Colorado, Feiken et al found that children with personal exemptions to immunization were 22.2 times more likely to acquire measles and 5.9 times more likely to acquire pertussis than vaccinated children.[8] In general, the greater the number of exempted persons, the higher was the incidence rate of both measles and pertussis in unvaccinated children.

Staff at the Centers for Disease Control and Prevention identified 13 outbreaks of measles in the period 1985–1994 in religious groups opposing immunization. These outbreaks resulted in more than 1,200 cases and 9 deaths (CDC, written communication from Robert Snyder, BA, April 1997). Outbreaks of polio (in the 1970s), pertussis, and rubella have been documented among Amish groups.

Generally, school laws have been shown to be very effective. A meta-analysis demonstrated reduced disease incidence associated with immunization requirements in six of nine studies.[9] Furthermore, three studies demonstrated improved coverage rates after requirements were implemented. The evidence of effectiveness applies to most children and young adults.

Most vaccines provide both individual and community protection. Most of the diseases against which we vaccinate are transmitted from person to person. If a large enough proportion of individuals in a community is immunized, this proportion serves as a protective barrier against transmission of the disease in the community, thus indirectly protecting those who are not immunized for whatever reason as well as those few who received vaccine but are not protected (vaccine failures). The proportion of the population that must be immune to provide this herd immunity varies according to the infectiousness of the agent. For poliomyelitis, it is considered to be on the order of 80%, whereas for measles it is in excess of 90%. When a community has a high level of vaccination, an individual might decide not to be vaccinated in order to avoid the small risk of adverse events while benefiting from the vaccination of others. Of course, if a sufficient number of individuals make this decision, the protection levels in the community decline, the herd immunity effect is lost, and the risk of transmission rises. Since approximately 11,000 infants are born every day in the United States, immunization coverage is not static; there is an ongoing need to

ensure that children continue to be protected. Additionally, a continuing threat of importation of disease from other countries exists.[10]

School immunization laws reflect the delicate balance between the rights of the individual to determine his/her own fate and the rights of society to ensure that all members of society participate in community protection. A decision by a parent not to vaccinate his or her child is a decision to put at risk not only that child but the rest of the community as well, since there are many who would like to be protected but are not. These unprotected groups include children too young to be vaccinated, those with medical contraindications to vaccination, and the small proportion of those who have been vaccinated but were not protected. In some sense, persons who do not have their children immunized are getting a "free ride" without putting their children to the very low risk of an adverse event, because they are benefiting from the impact of the vaccination of others.

Challenges to mandatory immunization laws based on religion or philosophical belief have led various courts to hold that there is no constitutional right either to religious or philosophical exemptions.

State Health Department Considerations

Several important aspects of school immunization requirements must be taken into account by a state prior to enacting a school or day care entry requirement: the effectiveness of school mandates, the appropriateness of the requirement, and implementation and enforcement issues.

A decision about the appropriateness of an immunization requirement is generally based on national recommendations from groups like the Advisory Committee on Immunization Practices and the American Academy of Pediatrics. Input from the local medical community is also critical. The population at risk for a vaccine-preventable disease should be compared with the population that would be vaccinated under a school entry requirement as a means of determining the impact of a potential immunization requirement. Also, serious diseases transmitted by the airborne route in school-aged populations generally get the highest priorities for immunization requirements. The benefits of an immunization requirement must also be weighed against the side effects of a vaccine.

The legal processes to establish new requirements vary from state to state. However, the timing of the decision, the cost of the vaccine, and state purchase requirements are universally important to the implementation of new school requirements. States must be in a position to ensure that all students in the state have access to vaccine, without financial barriers. Furthermore, it is important that providers, parents, and schools be notified well in advance of any changes in school and daycare entry requirements.

Prior to implementation of school laws, consideration of how the law will be enforced is necessary in order to ensure that the law is effective.

It must be decided before a new law or regulation goes into effect whether only children enrolling in school for the first time are covered or whether all students, regardless of time of enrollment, must be vaccinated. Exclusions of unvaccinated students from school could be considerably greater if the law includes all states.

Legislative Considerations for Childhood Immunizations: One State's Experience

At the legislative level, it must be recognized that the ability to compromise is essential. For example, this need to compromise, a key aspect relating to parents seeking exemptions from state school laws for their children, has arisen on a number of occasions in Idaho. In 1979, Idaho had legislation that did not allow philosophical exemptions from immunization. However, the Idaho legislature could also reject executive rules through a resolution. To address increasing concerns about immunization and the potential use of an associated resolution, the state passed revised legislation in 1991 containing a major exemption option. Specifically, this option involved legislative language that allowed

exemption from state immunization laws on "other grounds." Thus, essentially a blanket exemption was available to parents concerned with vaccination.

Compromise was also necessary in passing immunization registry legislation in Idaho. In 1999, legislation to establish a state registry passed, but it included the compromise that participation in the state's system was voluntary. The two major perspectives in these debates and in those compromises tended to be those of the state health agency and various scientists, on the one hand, and those of individuals opposed to vaccination or else questioning the safety of vaccines, on the other.

This experience in one state demonstrates that the public health community must recognize that there are political considerations associated with childhood immunization laws that cannot be ignored. This political dimension will continue to pose a challenge to those who seek to minimize the incidence of vaccine-preventable diseases.

Conclusion

The role of law in protecting the public's health is critical in the area of childhood immunizations. The effectiveness of childhood immunizations in preventing outbreaks of contagious diseases is well documented. Nevertheless, public health officials and supportive legislators continue to struggle to gain passage of comprehensive laws that mandate childhood vaccinations for all. Opponents' claims of civil liberties violations and the tendency of the few to avoid immunizations for their children for various reasons continue to pose an obstacle to complete elimination of many childhood diseases.

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Immunization for Seniors

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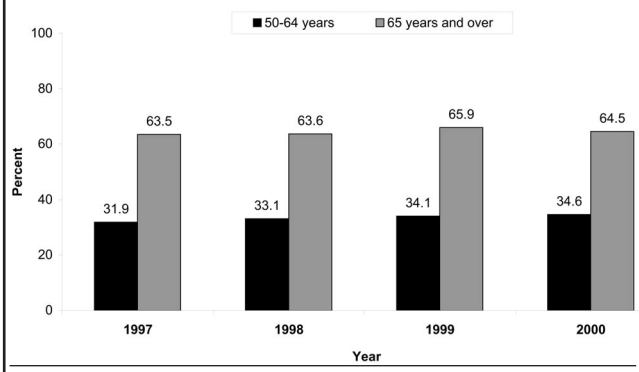
ABSTRACT

Vaccine-preventable diseases remain a significant health problem for adults in the United States. Far more adults die from the complications of vaccine-preventable diseases than do children in this country. Available vaccines that are effective in preventing morbidity and mortality from these conditions are underutilized, and significant racial and ethnic disparities in rates of utilization of adult vaccines persist. A variety of important vaccine-preventable diseases affect seniors. However, influenza and pneumococcal infections stand out as being responsible for more cases and more deaths each year among seniors than all other vaccine-preventable diseases in the United States combined. Current vaccination rates for these two diseases are far short of the *Healthy People 2010* target rates of 90% immunization of the population of adults aged 65 years or over. Despite state efforts to improve vaccination rates of seniors, efforts that have included regulatory and educational approaches, significant challenges remain in designing immunization programs for seniors that are universally effective.

Each year in the United States, 50,000–90,000 adults die of vaccine preventable diseases.[1] The number of adults who die of vaccine preventable disease far exceeds the number of children who die from these conditions.[1,2] Despite the fact that cost-effective adult vaccines prevent morbidity and mortality from these conditions, these vaccines are underutilized. The General Accounting Office (GAO) recently reported to Congress that while the use of preventive services (including adult vaccines) offered under the Medicare Program has increased over time, use of these services varies. In addition to considerable differences in use between states, there is also marked variation in use of these services by racial and ethnic group, income, and educational level.[3] As noted by the GAO, the differences in utilization of preventive services among racial and ethnic groups were greatest for immunizations.

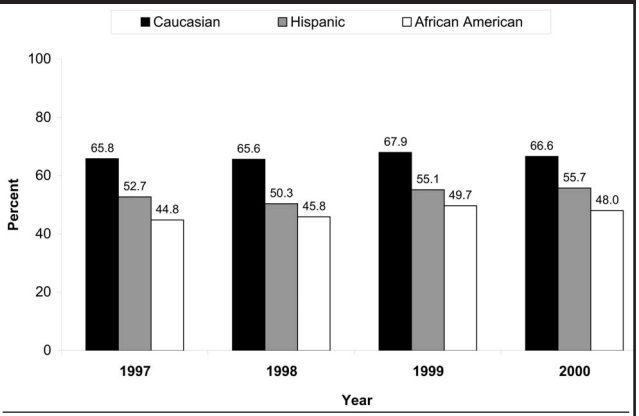
The majority of adult deaths from vaccine-preventable diseases is due to influenza and pneumococcal disease. Data collected by the Centers for Disease Control and Prevention (CDC) in the National Health Interview Survey[4] and the National Nursing Home Survey[5] demonstrate the underutilization of vaccines for these two diseases.

Figure 1. Proportion of adults who received



Source: Centers for Disease Control and Prevention. Early release of selected estimates from the National Health Interview Survey (NHIS). Data from January - June 2001. http://www.cdc.gov/nchs/nhis.htm (accessed 6/27/02).

Figure 2. Influenza vaccination coverage levels by race/ethnicity

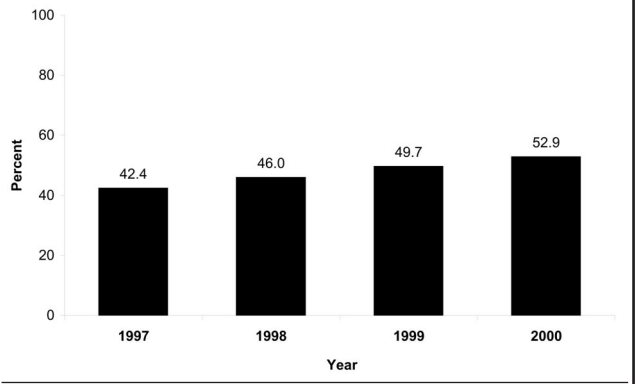


Source: Centers for Disease Control and Prevention. Early release of selected estimates from the National Health Interview Survey (NHIS). Data from January - June 2001. http://www.cdc.gov/nchs/nhis.htm (accessed 6/27/02).

Even though the disparity by race and ethnic group in childhood vaccination rates has decreased steadily over the past ten years, significant disparities remain for adult vaccination. Surprisingly, vaccination rates of one of the highest-risk populations of patients—those in long-term care settings and nursing homes (Figure 5)—are far below the target rate of 90% set in *Healthy People 2010*.[6]

As often is the case, efforts to address underuse of preventive services—particularly vaccination—follow disease outbreaks. In February 1996, there was an outbreak of multidrug-resistant pneumococcal pneumonia among residents of a rural Oklahoma nursing home. Pneumonia developed in 11 of 84 residents, three of whom died.[7] On investigation by local and state health department officials and the CDC, only three of the 84 residents had documentation of ever receiving the pneumococcal vaccine. Subsequent to the outbreak, the Oklahoma State Department of Health issued regulations that require all licensed nursing homes to offer influenza vaccine annually to each resident and employee and to offer pneumococcal vaccination to all residents. In addition, the regulation allows attending physicians to establish standing orders for these vaccines, in accordance with the recommendations of the Advisory Committee on Immunization Practices (ACIP).[8]

Figure 3. Proportion of adults aged 65 years and over who have ever received the pneumococcal vaccine



Source: Centers for Disease Control and Prevention. Early release of selected estimates from the National Health Interview Survey (NHIS). Data from January - June 2001. http://www.cdc.gov/nchs/nhis.htm (accessed 6/27/02).

This article's objective is to highlight the burden of vaccine-preventable diseases in seniors and to provide insights from state and federal efforts to improve immunization of this population.

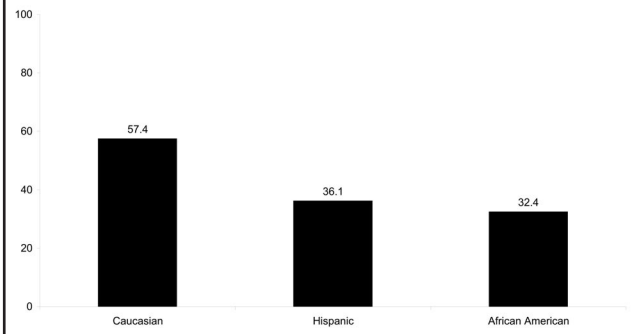
Immunization for Seniors: An Overview

Vaccine-preventable diseases are responsible for substantial morbidity and mortality in the United States and worldwide. Important vaccine-preventable diseases include influenza, pneumococcal disease, hepatitis A, hepatitis B, measles, mumps, rubella, pertussis, and tetanus. All age groups are affected, including the elderly.

Influenza and pneumococcal infections stand out as being responsible for more cases and more deaths each year than all other vaccine-preventable diseases in the U.S. combined. The elderly are particularly vulnerable to serious complications of these two diseases, including hospitalization and death.

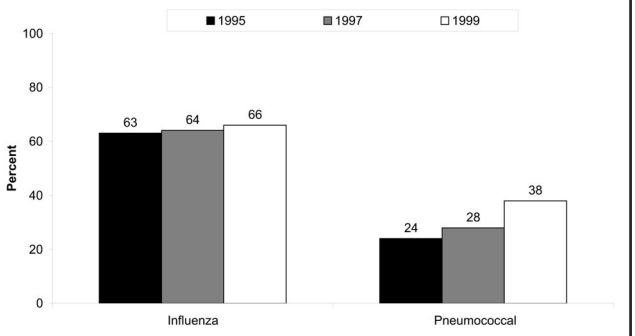
Influenza is an acute upper respiratory tract illness that may be associated with complications such as secondary bacterial infections and exacerbations of underlying medical conditions that may result in hospitalization or death. Approximately 10–20% of the population becomes ill with influenza each year, with an annual toll of 25–50 million cases. Infection with influenza results in 100 to 200 million days of illness, tens of millions

Figure 4. Proportion of adults aged 65 years and over who have ever received the pneumococcal vaccine, by race/ethnicity, U.S. 2000



Source: Centers for Disease Control and Prevention. Early release of selected estimates from the National Health Interview Survey (NHIS). Data from January - June 2001. http://www.cdc.gov/nchs/nhis.htm (accessed 6/27/02).

Figure 5. Documented influenza and pneumococcal vaccination rates of nursing home residents



Source: Buikema AR, Singleton JA, Sneller VP, Strikas RA. [abstract]. Influenza and pneumococcal vaccination in nursing homes, U.S., 1995-1999. Centers for Disease Control and Prevention. 35th National Immunization Conference. 2001

of days of work and school absenteeism, hundreds of thousands of excess hospitalizations, tens of thousands of excess deaths, and billions of dollars in direct and indirect costs.

Influenza vaccine is safe and effective.[9] Among elderly persons, the benefits of vaccination include reductions in hospitalizations and deaths and health care cost savings. In one six-year serial cohort study in a Minneapolis–St. Paul area health maintenance organization, influenza vaccination of the plan members was associated with a 39% reduction in hospitalizations for pneumonia or influenza, a 32% reduction in hospitalizations for all respiratory conditions, a 27% reduction in hospitalizations for congestive heart failure, and a 50% reduction in deaths from all causes.[10] Administration of the influenza vaccine was also associated with cost savings of $73 per person vaccinated. Other studies have also demonstrated reductions in hospitalizations and deaths as well as cost savings.

Pneumococcal diseases are also important causes of morbidity and mortality. Pneumococcal pneumonia is responsible for 100,000–175,000 hospitalizations and 7000–12,000 deaths each year.[11] Invasive pneumococcal disease is responsible for 50,000 cases of bacteremia and 3,000 cases of meningitis each year.[12]

Immunization with the pneumococcal polysaccharide vaccine provides substantial benefits for the elderly.[12] Observational studies have shown that, among elderly persons, vaccination reduces bacteremic infections by about 75% and is associated with cost savings of about $8.27 per person vaccinated.[13] A two-year cohort of elderly persons with chronic lung disease suggested that the benefits for this group might be even greater. In that study, vaccination was associated with a 43% reduction in hospitalizations for pneumonia, 29% fewer deaths, and cost savings of $294 per person vaccinated.[14]

Clearly, the burden of disease and the benefits of vaccination suggest that influenza and pneumococcal vaccinations should be administered to all elderly persons. However, many persons aged 65 years and older in this country have not yet received the protection that could be afforded by these vaccines. In 2001, only 64.3% of the elderly had received an influenza vaccination, and only 53.5% had ever received a pneumococcal vaccination.[4] These rates are far short of the *Healthy People 2010* goal of vaccinating 90% of this population against these diseases.[6]

Critical factors for successful vaccine delivery relate to issues important to patients and to providers, as well as vaccine supply and reimbursement issues and local and national policy. A systematic review by the Task Force on Community Preventive Services identified a number of strategies that have demonstrated effectiveness for enhancing vaccination rates.[15] These strategies emphasize increasing demand for

vaccination (e.g., through reminders to patients, education, and regulation); enhancing access to vaccination (e.g., through reduced cost for preventive services and special clinics); and addressing provider barriers (e.g., through implementation of reminder/recall programs, performance feedback, and standing orders). A recent meta-analysis of clinical trials that assessed interventions to increase vaccination rates for adults found that organization changes were the most effective type of intervention.[16] Standing orders that may exist within such changes are particularly deserving of attention.

Standing orders exist in programs in which non-physicians deliver vaccinations without the direct involvement of the physician at the time of the visit. The standing orders are established through policies and protocols and may be carried out in clinics, hospitals, and nursing homes. Because of their high level of effectiveness in various settings, standing orders have been strongly recommended as especially effective organizational interventions by the ACIP.[8]

State-level Challenges—An Example from Montana

Montana has the fourth fastest growing population of adults aged 65 years and older. It is considered a frontier rural state. In many small communities, over 50% of the residents are 65 or older. The fastest growing segment in that group consists of adults 80 years and older. Providing health care for the population is of primary concern, as 18.5% of the citizens have no insurance coverage. Many seek medical attention only when a problem has become a crisis. This situation leaves hospital emergency rooms to provide primary care, the highest priced care available. Little is done to prevent disease in economically depressed social situations, and people in such settings do not have the income to obtain routine health care. The emphasis in Montana has been to cover children through the Children's Health Insurance Program (CHIP) and to offer expanded qualifying criteria for participants. This program has been very successful, but state budget problems are placing this program on the chopping block in an upcoming special session of the legislature.

Immunization of seniors has not become a requirement by statute in Montana—a state that meets in legislative session only every other year. In the 2001 session, a bill that would have required immunization of nursing home residents for influenza and pneumococcal disease was defeated by efforts of the nursing home industry, whose advocates argued that they did not want an additional state mandate.

In the absence of legislation, the Montana Department of Health (MDOH) has mounted an educational program that includes using public service announcements, participating in AARP programs, and working with aging services, the legacy legislature, and other groups to provide information to seniors about the importance of vaccination. In addition to informing seniors of the need for vaccination, MDOH has suggested to nursing homes, assisted living programs, and hospitals that they recommend immunizations for all residents and nursing personnel; MDOH has also recommended that vaccination become a required condition of employment at these organizations. As a part of the educational efforts, nursing homes have done a good job of notifying the public of the dangers of bringing infection into a facility and thus placing senior residents at risk. A visitor with cold or flu symptoms is asked to refrain from entering the facility and exposing the patients to the infection.

Since Medicare Part B pays for influenza and pneumococcal vaccines plus administration fees, it is difficult to imagine why this at-risk population does not take full advantage of being immunized. Immunization should be offered in every case in which the health care provider accepts Medicare payments, as nearly all providers in Montana do. Finally, MDOH and others have had discussions with Montana's congressional delegation to suggest or mandate that the Social Security Administration include information about influenza and pneumococcal vaccinations in the August, September, and

October social security check envelopes, in the hope that seniors would make appointments to get their flu and pneumococcal shots prior to November of each year.

In addition to influenza and pneumococcal vaccinations, Montana public health clinics recommend vaccination for seniors at risk for hepatitis A and B; keeping immunization records current; assuring boosters for tetanus and diphtheria; and rubella and varicella (chickenpox) vaccinations for those not previously exposed. Part of Montana's efforts to combat vaccine-preventable diseases is a result of assistance from the CDC. For example, when 11 deaths in one community occurred as a result of an outbreak of hepatitis C in a group of ex-offenders who were sharing needles, CDC assistance allowed state public health authorities to mount a quick response in education and outreach to a minority population that would not normally obtain medical assistance or seek advice until there was dire need.

Other issues in Montana health care deserve mention. For example, the last session of the Montana legislature passed a bill that allows nursing homes and assisted living programs to donate unused medications, packaged in blister packs, to public health clinics. After checking for tampering and ensuring proper expiration dates, the clinics give the medications to low-income individuals in need of them. In addition, Montana passed a bill tacking a 25-cent surcharge on every license plate sold in the state, with the proceeds used for distribution of transportation services for seniors and the disabled; this funding assists many in small rural communities who cannot drive and have long distances to go for medical attention and other necessities.

The slogan "Disease is Bad—Vaccine is Good!" has real meaning in Montana. In 1883, smallpox outbreaks were the catalysts for the creation of Montana's public health system. It is a tribute to Montana's public health department as well as to other public health organizations across the country that there has not been a single case of smallpox reported since October of 1977. The same kind of attention to other vaccine-preventable diseases can achieve a better quality of life not only for seniors but also for all other citizens.

Implementation of a State Vaccination Regulation: Initial Results from a Hospital Survey

Hospitalized patients are at particular risk for subsequent influenza and pneumococcal disease.[17] More than 40% of subsequent influenza-related hospitalizations and approximately two-thirds of influenza related deaths occur in elderly persons who have been previously discharged during that flu season.[18] Similarly, up to two-thirds of patients hospitalized with serious pneumococcal infections have been recently hospitalized.[19–23] Despite the risk of subsequent disease, vaccination is rarely offered to hospital patients,[8,17,24–26] The ACIP and other organizations recommend hospital-based vaccination against influenza and pneumococcal disease.[8–9,12,17]

In 1999, the New Jersey Department of Health and Senior Services (NJDHSS) issued regulations that require hospitals to offer influenza vaccination (between October 1, or earlier if the vaccine is available, and February 1 of every year) to every patient aged 65 years or older.[27] In addition, the regulations require that every patient aged 65 years or older be offered vaccination against pneumococcal disease, in accordance with the recommendations of the ACIP. For both vaccines, the regulation requires that either receipt of the vaccination or refusal be documented in the patient's chart and made a part of the permanent hospital record. Hospitals are required to report data on the number of vaccinations administered annually.

In spite of the requirement that hospitals and nursing homes in New Jersey offer vaccinations and vaccinate patients, regulations alone may be inadequate to ensure immunization. In April 2001, nine cases of pneumococcal pneumonia were reported in a New Jersey nursing home.[28] In a case-control study conducted by the NJDHSS, illness was strongly associated with a lack of

documentation of receipt of the pneumococcal vaccine (none of the nine cases had documentation of vaccination). A review of the hospital medical records of seven of the affected residents also demonstrated absence of pneumococcal vaccination as required.

Recently, a survey of infection control practitioners in New Jersey hospitals was conducted to evaluate implementation of the vaccination regulation. The main result of the survey was that overall success of implementation was very low. Among respondents, 43.9% reported that 25% or fewer of their hospital inpatients aged 65 years and older went through the vaccination protocol appropriately. The majority of respondents (66%) reported that "most physicians" did not agree with the scope or nature of this regulation, and these respondents documented a variety of reasons given for physicians' lack of agreement. Preliminary results of a multivariate analysis of the survey suggests that specific implementation practices were not predictive of success, that smaller and less urban hospitals were more likely to be successful, and that doctors' opinions and attitudes were the most important determinants of successful implementation of the regulation.

Conclusion

Despite the availability of immunizations that can prevent the morbidity and mortality of vaccine- preventable disease, such immunizations are underutilized. The numbers of seniors who die from vaccine-preventable disease far exceeds the number of childhood deaths from vaccine-preventable disease. Initial efforts at the state level have met with varied success in improving vaccination rates for adults. It is likely that the development of effective vaccination programs for adults will require a multifaceted approach that includes legislative and regulatory efforts, educational efforts, and organizational interventions.

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The Legal Context of Mosquito Control for West Nile Virus in New York City

Wilfredo Lopez, James R. Miller

ABSTRACT

When New York City became the first area in the United States to experience an outbreak of West Nile Virus, the New York City Department of Health and Mental Hygiene assumed responsibility for responding to the threat. That department's actions in spraying and taking other actions to control the mosquitoes that spread the disease to humans encountered significant opposition from various environmental groups. Moreover, complying with existing law that governed mosquito control activities became a challenge. This article provides an overview of the department's experience in responding to the threat posed by West Nile Virus. That experience reinforces the importance of a public health organization's collaborating with public health lawyers to produce a better public health outcome.

West Nile Virus (WNV) is one of a number of microorganisms spread to humans by the bite of an infected mosquito. Although most WNV infections are mild or cause no symptoms,[1] severe WNV infection involving the brain (encephalitis) may cause long-term disability[2] or death.[3] WNV has spread throughout much of the eastern half of the United States[4] following its unexpected arrival in the New York City (NYC) area in 1999.[5] It has now spread to many western states. In 1999, 2000, and 2001, NYC experienced 45, 14, and 7 severely ill persons, respectively, including 5, 1, and 0 deaths. Responsibility for the surveillance and control of mosquito-borne infections in NYC rests primarily with the NYC Department of Health and Mental Hygiene (the Department). In addition to undertaking public and professional outreach, the Department has acted throughout NYC to reduce the risk of human WNV infection by either eliminating mosquito breeding sites or by treating breeding sites to prevent developing (or larval) mosquitoes from emerging as biting adults, and by spraying pesticides to reduce the number of adult mosquitoes in selected areas determined to be at an increased risk for human WNV infection. This article summarizes the legal and regulatory context of larval and adult mosquito control to address WNV.

Mosquito Breeding

Many mosquito breeding sites are located on private property. Mosquito eggs hatch only in stagnant or slowly moving water. While stagnant water occurs naturally, urban environments have numerous artificial containers that hold water and support mosquito breeding—e.g., clogged roof gutters, used tires, buckets, neglected swimming pools, flower vases in cemeteries. Because locally acquired mosquito-borne disease had been rare in NYC for decades prior to the 1999 introduction of WNV, the Department initially focused on educating the public with community presentations, press releases, and posters regarding the potential for mosquitoes to breed in artificial containers on property. Following this initial information campaign, the New York City Board of Health passed a resolution in 2000 stating that standing water favors mosquito breeding and constitutes a

public health nuisance.[6] The resolution was published in a general circulation daily newspaper, and five days later, the Department gained the authority to have immediate access to private property to inspect for standing water and to apply larvicide where needed. Most reports of standing water are made by the public via telephone and the Department's Website. The Board of Health resolution also provided authority for issuing notices of violation and collecting fines, an authority of which the Department has made increasing use.

Pesticide Use

Pesticide use is regulated by federal, state, and local laws. Two major types of pesticides are used for mosquito control: larvicides (products placed in water to kill developing mosquito larvae) and adulticides (products used to kill adult mosquitoes, generally by being sprayed into the air). Because WNV's arrival in 1999 was unexpected and its return in 2000 was uncertain, pesticide application in NYC during 1999 and 2000 occurred under emergency conditions, and NYC was exempted from requirements of the State and City Environmental Quality Review Acts (SEQRA and CEQRA, respectively). Following the second year of WNV transmission in NYC in 2000, the Department recognized that WNV transmission in subsequent years was to be expected and that pesticide application for larval and adult mosquitoes would no longer occur under emergency exemptions. The Department then initiated an environmental review of pesticide use and applied to the New York State Department of Environmental Conservation (DEC) for pesticide permits.

SEQRA and CEQRA require that a governmental entity conduct an environmental review when it engages in an activity that may adversely effect the environment. Upon completion of such a review, the government entity issues either a Negative Declaration, indicating that an adverse environmental impact is not likely, or a Positive Declaration, if the potential for adverse effects exists. NYC issued a Negative Declaration for its intended use of larvicides[7] and a Positive Declaration for adulticide use. An Environmental Impact Statement (EIS) was prepared on potential adverse effects from adulticide use on human and environmental health. The EIS concluded that while adulticides have the potential to cause skin, respiratory, and eye irritation, the overall risk to human health due to adverse effects from the spraying of adulticides is less significant than health effects due to mosquito-borne infection if adulticides are not sprayed.[8] The EIS also determined that aquatic crustaceans (e.g., barnacles, shrimp) in a tidal bay could be harmed if adulticides were applied in the tidal bay's drainage area immediately before a heavy rain.[8]

The primary federal law governing pesticide use is the Federal Insecticide, Fungicide and Rodenticide Act of 1947 (FIFRA). FIFRA, as well as state law, requires detailed record-keeping of date, location, and amount of pesticide applied, and annual reporting of pesticide usage.[9] FIFRA and state law also require training, certification, and protection of pesticide applicators. NYC contracted for larvicide and adulticide application in 2000. DEC determined that the contractor used inadequately trained workers to apply pesticide and imposed a $1 million fine.[10] The federal Occupational Safety and Health Administration cited the contractor for failing to adequately protect worker health and safety. In 2001, Department employees, after being properly trained, applied larvicide and adulticide.

FIFRA requires that pesticides be labeled with information regarding their use and that applicators follow label instructions during application—in other words, "the label is the law."[11] The label for Anvil 10+10", the adulticide used in NYC during 2000–2001, includes statements that Anvil 10+10" may not be applied "directly to water" and that "applications should be made when wind is less than10 MPH."[12]

In obtaining pesticide permits from DEC, the Department developed detailed procedures to comply with legal requirements, label conditions, and EIS findings. To meet the requirement for public notification prior to spraying,[13] the

Department issues press releases prior to each adulticide application. Two New York Police Department cars escort each adulticide spray truck and broadcast a recorded message informing bystanders that pesticide application is occurring. On at least two occasions, the Department has obtained a waiver from the New York State Health Commissioner to apply pesticide in NYC parks without providing the public at least 24 hours prior notice, but on both occasions the park was closed to the public during pesticide application. Protests, including attempts to physically block spray trucks and to be present in closed parks during application, have occurred.

The Department monitors temperature and wind speed throughout pesticide application. The Department does not apply pesticide within 100 feet (by truck, or within 300 feet by helicopter) of rivers, ponds, and streams. The Department conducts pre- and post-application water tests to check for the presence of pesticides in selected bodies of water. The Department does not apply pesticide if the weather forecast includes at least a 50% chance of significant rainfall. Park rangers monitor for fish kills in the 24 hours following pesticide application. The Department uses global positioning satellites to track spray truck and helicopter flight routes to assist in creating a record of where pesticide application has occurred.

While the Department is not required to do so, the Department has monitored for adverse human health effects associated with pesticide use by (a) encouraging affected persons and their physicians to report symptoms to the NYC Poison Control Center (PCC), (b) contacting physician offices and hospital emergency departments in areas where pesticide application has occurred, and (c) determining if ambulance calls and emergency department visits for asthma or respiratory illness are increased in the 48 hours following pesticide application. Individual reports of eye and respiratory tract irritation have been received at PCC, but other monitoring has not detected an increase in adverse human health effects.

The decision to use pesticides to reduce the risk of human WNV infection is based primarily on collection and laboratory testing of adult mosquitoes. The Department currently has 92 mosquito trap sites throughout NYC. Adult mosquitoes are collected weekly from each location and then sorted by species and tested for evidence of WNV. Areas are selected for pesticide treatment based primarily on the number and rate of WNV infection among adult mosquitoes, especially among those species that bite humans. Details regarding the Department's stepwise approach to pesticide use may be found in the Department's Comprehensive Mosquito Surveillance and Control Plan.[14]

The No Spray Coalition, the National Coalition Against the Misuse of Pesticides, and other parties attempted to stop adult mosquito control in NYC by seeking an injunction and a restraining order against the Department in federal court. The court denied both motions. The plaintiffs alleged that pesticide application for mosquito control violates the Resource Conservation and Recovery Act (RCRA) and the Clean Water Act (CWA). The court has dismissed the plaintiff's claim regarding RCRA,[15] and the lower court's action was upheld on appeal.[16] A trial regarding the plaintiff's claim under CWA is pending. FIFRA, unlike RCRA and CWA, does not allow citizen actions in federal court.

While the federal lawsuit illustrates opposition to adulticide application, the other end of the spectrum is illustrated by two notices of claim filed in 2001 in Nassau County, New York, alleging the wrongful death of two individuals from WNV infection due to the Nassau County Health Department's failure to apply adulticides.

Conclusion

Public health actions to prevent and control WNV infection take place in the context of multiple laws and regulations. Not complying with environmental laws and regulations may adversely impact human (especially worker) health and the environment, result in fines, and elicit legal action by anti-pesticide organizations. Communicable disease control practitioners will benefit by collaborating with public health lawyers, and

their collaboration will result in a better public health outcome.

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The Impact of Laws on HIV and STD Prevention

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ABSTRACT

HIV and sexually transmitted diseases (STDs) are major public health problems in the United States. Since the start of the epidemic, nearly 800,000 persons have been reported with AIDS, and approximately 900,000 Americans are currently living with HIV infection. Each year, 15 million people in the United States become infected with one or more STDs. The direct and indirect costs of the major STDs—not including HIV infection—and their complications are estimated to total at least $10 billion annually. This article underscores the importance of law and other structural factors in the prevention and treatment of HIV and STDs. It describes state-level laws on STD screening, name-based reporting of STDs, name-based reporting of HIV and HIV partner notification implementation, and the impact of laws on STD and HIV risk behaviors and prevention services. More broadly, the article focuses on how the law influences the vulnerability or resilience of persons facing the risk of STDs, HIV infection, or AIDS.

The role of law in HIV and STD prevention and control is important because of the impact of these diseases. At an individual level, these can be devastating diseases, some lasting a lifetime. At the level of public health, HIV and the STDs are major problems in the United States. Despite the introduction of HIV treatments in 1996, AIDS and HIV remain at epidemic levels. Since the start of the epidemic, nearly 800,000 persons have been reported with AIDS, and half of those are known to have died. In the last twenty years, AIDS has increased most dramatically among women and minorities, and AIDS deaths have been strongly associated with poverty and with minority and female status. It is estimated that approximately 900,000 Americans are currently living with HIV infection and that roughly half of these are untested, untreated, or both. Rates of new infections have been high and stable since the early 1990s.[1]

STD rates are even higher. Each year, 15 million people in the United States, of which one-fourth are teenagers, become infected with one or more STDs. Chlamydia is the most common of all bacterial STDs, with an estimated three million new cases occurring each year. Gonorrhea is on the rise for the first time in twenty years, and an estimated 650,000 new cases occur each year in the United States. Yearly incidence rates for other STDs are one million for herpes and over five million for human papillomavirus. The direct and indirect costs of the major STDs, not including HIV infection, and their complications are estimated to total at least $10 billion annually.[2]

Efforts to curb HIV and STD incidence occur largely at the state level. The first three of the following sections provide descriptions of efforts in Georgia, Florida, and New York, respectively. A final section addresses the impact of law on the HIV pandemic.

Legislation to Address the Incidence of Chlamydia in Georgia

The passage of Georgia's Chlamydia Screening Bill[3] into law followed a multi-year effort driven by public health officials, legislators, and health and women's advocacy groups to improve the health of women in the state.

A challenge of diagnosing chlamydia is that eighty percent of infected women are asymptomatic, and a clinical examination may not always reveal the presence of the disease. The complications of untreated chlamydia in women can lead to ectopic pregnancy, pelvic inflammatory disease (PID), and even sterility. Ectopic pregnancy is a leading cause of maternal death among African-American women in Georgia, and Medicaid costs for treating the complications of ectopic pregnancy are high. In Georgia, a clear need for a statewide program to detect and treat chlamydia existed.

Dr. Kathleen Toomey, Director of Georgia's Division of Public Health, was largely responsible for launching the initiative that led to the bill's passage. As a federal health officer, Dr. Toomey observed and treated chlamydia and its effects among native women in Alaska. Her advocacy led to a screening protocol and a 75% reduction in the incidence of chlamydia in that population. As Georgia's state epidemiologist, she secured federal funding to conduct pilot screenings that revealed an incidence of chlamydia among teen-age girls as high as 15% of those tested in some locations in the state. The pilot screenings further revealed that the disease in young women was commonplace across the state, in small towns as well as urban populations.

These findings sparked the Georgia Legislative Women's Caucus to explore the availability of screening and treatment for chlamydia for Georgia women. With assistance from the American Social Health Association and women's advocacy groups in Georgia, a Georgia STD coalition was formed and remained active throughout the efforts to pass the legislation. In 1997, the Georgia legislature passed a resolution creating a Study Committee on Infectious Diseases, which engaged a broader grouping of legislators in learning about the threat and costs of untreated chlamydia in Georgia. The committee determined that Georgia taxpayers were paying annually more than $51 million for chlamydia complications, $124 million[a] for PID alone, and $59 million for hospitalizations of chlamydia cases.

The primary recommendation of the Study Committee was to address the need for screening of at-risk populations. Legislation was drafted and filed in 1998 to provide that all Georgia insurers include as basic coverage an annual chlamydia screening for women under the age of 30. The fact that chlamydia infection creates a gateway opportunity for the spread of both gonorrhea and HIV infection lent an additional urgency to the message given to the state's budget writers.

As the bill moved forward, insurance and business lobbyists firmly opposed its passage. Some legislators based their opposition on the belief that these diseases result from illicit sexual behavior and that state funds should not be used to "support" such behaviors. This powerful opposition was overridden by the combination of the sobering costs of the disease, the commitment of the Women's Caucus to passage of the bill, the building of an active and broad STD coalition, and the advocacy of key, influential players. The Georgia chlamydia screening insurance legislation became law in July 1998. In addition, the state budget included funds for the state public health initiative to provide screenings for at-risk uninsured women in public health clinics.

The progress on this particular STD issue created a precedent for public policy discussion of a formerly sensitive topic. The breaking of the ice, so to speak, helped create a climate for passing contraceptive equity legislation in 1999. This legislation requires that all insurance prescription plans include coverage of prescribed FDA-approved contraceptives, another step forward for positive public health policy in Georgia.

HIV Name-Based Reporting in Florida

In 1999, over some vigorous political opposition, the Florida legislature passed a law that

provided for name-based reporting of HIV cases in the state. The new law required state health department staff to ask permission of private providers in order to offer Partner Counseling and Referral Services (PCRS) to HIV infected persons. One impact of this provision was a loss of STD services staff because of the 20% increase in workload that the mandated contact with private providers created. Yet another impact was that different cities in Florida had very different PCRS implementation rates because of the variable efficacy of AIDS/HIV surveillance offices in obtaining permission from private providers to offer PCRS. For example, in one year, Miami's PCRS rate was 31%, compared to 100% in Orlando. In June 2001, this obstacle to widespread effective implementation of PCRS was removed from the legislation. Contact with private providers prior to initiation of PCRS is now a courtesy, as with all other STDs, not a requirement.

The success of the implementation of the HIV name-based reporting law has been significant in terms of the numbers of both persons informed of exposure and new cases located and referred early to treatment. From 1996 to 2001, the private provider as a source of HIV-positive tests increased, from 5.4% to 21.5% of all such tests reported. Corrections facilities as a provider source increased from 2.5% to 7.9%. During 2001, 5,873 new HIV infections were reported in Florida. Of those, 58% (3,405) were assigned to STD services staff for follow up. Over 80% (2,755) of these positive persons were located, and 51.2% (1,411) of the located persons requested PCRS and accepted the offer of assistance to notify sex- and needle-sharing partners. Of the named partners, 67% accepted the opportunity for HIV testing. During the period 1997 to 2001, of the persons located and counseled regarding their exposure to HIV infection, the percentage of newly identified cases increased from 11% to 15.6%. Since the July 1997 implementation of HIV name-based reporting in Florida, 5,869 partners unaware of their exposure have been notified by the STD program staff.

With passage of the law, some feared that testing rates would be adversely affected, with increases in anonymous testing or even an overall reduction in testing rates. To the contrary, testing rates have continued to rise annually, with no change in the proportion of anonymous testing.

In addition to the HIV PCRS responsibilities in Florida, the STD staff workload in 2001 included a combined total of 24,012 positive tests for syphilis, chlamydia/gonorrhea, and perinatal hepatitis B. Local STD program staff worked to verify treatment of each of these positive STD reports. In addition to ensuring adequate treatment for clients diagnosed with a bacterial STD, the staff offered PCRS to a total of 2,797 high priority clients[b] who accepted the offer, with the result that 4,989 partners and other at-risk persons were assigned for follow-up services.

Although there have been obvious benefits from the implementation of this law, the name-based reporting program also has had some unintended consequences. Unforeseen negative impacts have included contradictory inter-state obligations and the financial cost created by insurance repeaters—those who make multiple requests for face-to-face counseling on the meaning of their test results and necessary changes in behavior. Some inter-state referrals receive no final disposition, a problem typical of more transient populations. In addition, health officials continue to struggle with how to cope with those they believe are sexual predators; in each case, health officials must balance the need to protect confidentiality against the need to release information that would expose the actions of these dangerous individuals. Staff retention also has been a major issue that will most likely continue to be problematic. In spite of such issues, the name-based reporting law has led to real public health benefits for Florida.

HIV Tracking in New York

In June of 2000, with passage of the HIV Reporting and Partner Notification Act (HIVRPN), New York became the 33rd state to require that HIV be tracked as a reportable

condition. New York may have also become the first state to explicitly integrate partner notification and reporting by statute. The New York Department of Health's AIDS Institute received funding from the Centers for Disease Control and Prevention to conduct a three-year research project to assess the public health impact of the legislation. The following comments outline the study's progress and current findings.

An Analysis of Data Collected in the New York State HIV/AIDS Surveillance and Partner Notification System

As of May 31, 2002, the electronic HIV/AIDS Surveillance and Partner Notification system has been fully developed and successfully implemented in all 62 counties in New York State. An initial data report, capturing all available information from program inception, June 1, 2000, through December 31, 2000, was released in early 2002.

The data show that a total of 16,866 HIV/AIDS cases with HIV-related laboratory testing or provider diagnosis from June 1, 2000 through December 31, 2000 were confirmed as HIV, HIV-related illness, or AIDS. Of the confirmed cases, 2,817 (17%) were initial HIV diagnoses, 9,036 (53%) were HIV illness diagnoses, and 5,013 (30%) had progressed to AIDS. A total of 12,144 cases, or 72%, were New York City residents, while 4,722 cases, or 28%, were from counties outside New York City. These preliminary totals will increase as surveillance follow-up is completed and additional cases are confirmed.

The gender, age and race/ethnicity distributions differed for newly diagnosed HIV as opposed to newly diagnosed AIDS cases. A greater proportion of females existed among the newly diagnosed HIV cases (41%), compared to the AIDS cases (30%). African Americans and Hispanics comprised approximately 85% of the HIV cases and 77% of the AIDS cases. The mean age of newly diagnosed HIV cases was also lower than the mean age of those diagnosed with AIDS.

A total of 2,342 partners of index cases tested from June 1, 2000 through December 31, 2000 were reported to the State Health Department. Medical providers reported that 46% of identified partners had been notified, either by the provider or through notification by the index patient. An additional 9% of partners were notified directly by New York State or New York City partner notification staff. Notification was in progress for an additional 3% of partners. Approximately 40% of partners were not notified because of insufficient locating information, out-of-state partner residence, partner death, or other mitigating circumstances. Finally, 2% of notifications were deferred because of the risk of domestic violence.

Measuring Aggregate Changes in HIV Testing Levels After the Implementation of the HIVRPN Regulations

The AIDS Institute staff obtained and analyzed counseling and testing as well as Medicaid data in order to determine changes in HIV testing levels after the implementation of HIVRPN regulations. Preliminary results of the analysis of these data indicate that, after adjustment for existing trends/drifts and autocorrelation effects in the series, no changes in HIV testing levels could be attributed to the implementation of the law and the associated regulations. Sub-group analyses (by age group, sex, race/ethnicity, region, and risk factor) also failed to indicate a measurable impact of the law/regulations on HIV testing levels. In addition, the staff has obtained HIV home testing data from Home Access, New York's only home HIV testing company. Analysis of these data will allow documentation of any impact of the legislation on the HIV home testing market in the state. Preliminary analyses are underway.

Use of Focus Groups of HIV/AIDS Consumers and Providers

To establish a more complete understanding of the social and economic losses that concern individuals regarding HIV testing and the issue of notifying partners, the AIDS Institute staff formed six focus groups consisting of HIV-positive individuals. To explore partner notification and domestic violence screening practices of providers, the staff formed two additional focus

groups consisting of HIV/AIDS service providers. Focus group sessions were conducted from August through December 2001. Preliminary findings from the focus groups reveal that:

1. Breaches of confidentiality and resultant stigma experienced by HIV-positive individuals were largely from within their own communities or informal networks rather than from service providers or government officials;
2. Focus group participants expressed a low awareness of the details of the partner notification law, or even awareness of "partner notification" as a formal concept;
3. Focus group participants reported little usage or awareness of the formal partner notification assistance programs operated by the departments of health of New York City and New York State;
4. Acknowledgement of the responsibility to notify partners varied by situation and partner type: there was little support for the need to notify past sexual partners, and there was virtually no recognition of the need to notify needle-sharing partners;
5. Participants reported both the potential for and the reality of violence resulting from being identified as HIV positive;
6. Participants felt entitled to the protection of the partner notification law, once that protection was explained to them; however, few reported knowing how to access the protection;
7. HIV service providers reported that initial concerns that the HIVRPN law might drive down HIV testing have been proven unfounded; and
8. Providers stated the belief that intimate partner violence was a major issue among HIV-positive clients and that more work to assist with intimate partner violence was being done by providers than was being reflected in reports to the health department.

Pilot Testing Through the HIV Testing Attitudes and Practices Survey (HTAPS)

To measure attitudes toward HIV testing as well as current practices among HIV-positive individuals, the AIDS Institute staff developed plans to administer a modified version of the CDC-funded HIV Testing Survey called the HIV Testing Attitudes and Practices Survey (HTAPS). Testing of HTAPS occurred in the summer of 2001.The survey was administered in Buffalo during the winter of 2002. The Buffalo survey data are being readied for analysis. Preliminary results suggest high levels of previous HIV testing among intravenous drug users (IDUs) and men who have sex with men (MSM) sub-samples, with lower rates exhibited among clients of STD clinics. Very few individuals who had not tested or who had delayed testing did so because they were concerned about their names being reported to the government. In fact, respondents indicated only moderate awareness of how HIV reporting worked in New York State and even less awareness about specifics of New York's HIV reporting and partner notification law. Respondents from STD clinics evidenced the lowest levels of awareness, while IDUs were the most informed of the three groups. Attitudes toward HIV partner notification also differed by venue. In general, MSM expressed the strongest reservations concerning the desirability, confidentiality, and efficacy of partner notification assistance programs, while the STD sub-sample was most accepting of these programs. Finally, intimate partner violence was reported in each interview setting, although the prevalence, frequency, and nature of abuse differed in each venue. HTAPS will be implemented in Rochester during the summer of 2002.

The Impact of Laws on the HIV Pandemic and on Individuals

Laws act as pathways for social determinants that impact HIV risk or resilience in multiple ways. Laws establishing eligibility requirements for Medicaid or State AIDS Drugs Assistance Programs can act as a mechanism through which poverty or low socioeconomic status translates into poor clinical care for persons with HIV, specifically delayed or intermittent access to anti-retroviral therapy. Laws also strictly limit

access to methadone to federally licensed clinics. Here, law serves as a mechanism for stigma by clearly identifying clients of methadone clinics as IDUs in the eyes of the community.

Ideally, criminal law and law enforcement act as tools through which society ensures public safety and strengthens communities by reinforcing norms of non-criminal behavior. Unfortunately, criminal law and policing can also act as pathways for determinants that negatively impact health and influence HIV risk. Substantial evidence demonstrates that drug control laws, as currently defined and enforced, have racially disparate impacts. Minorities, and particularly African Americans, are much more likely than Hispanics or whites to be stopped, arrested, and convicted for drug-related crimes and to serve longer sentences. Higher rates of incarceration for minority drug users translate into increased HIV risk because drug treatment in prison is inadequate in instances in which risky drug use and sex continue in prison. In addition, police activity disrupts social networks of drug users and sex workers and makes it more likely that drug use or sex will occur in high-risk settings. Mandatory minimum sentences for certain crimes ensure that some offenders, even first time offenders, will spend time in prison and be exposed to the risks inherent there. Strict enforcement of drug control laws, although intended to make communities safer, may actually increase community members' distrust of law enforcement and undermine communities' attitudes toward legitimacy of the law.

Law can also shape underlying social determinants of health, affecting socio-economic status and income inequality, attitudes toward race and racism (as laws may support stigmatization and isolation of ethnic groups), community and social organization, and specifically social capital and social cohesion. Law can also affect important resources such as housing and education that are closely linked to social determinants. Since social epidemiology demonstrates significant associations between many of these determinants and poor health, including elevated HIV risk, investigating laws' role in shaping these determinants matters.

Laws can also exacerbate existing social problems. For example, laws governing state-subsidized housing may actually increase homelessness to the degree that they deny housing where anyone in the family is convicted of drug use or else mandate residency requirements before families are eligible for state supported housing. Laws may also shape other important resources, such as access to education. Currently, anyone convicted of drug offenses becomes ineligible for federal student loans. Tax laws, welfare provisions, even debtor-creditor law may promote income inequality and thus exacerbate the effects that inequality has on health. The application of criminal laws that result in high levels of incarceration for minorities has also been labeled a "race-making" factor by some commentators. Disproportionate incarceration stigmatizes whole communities and promotes stereotypes of minorities, especially African Americans, in ways that can perpetuate racist attitudes among the non-African American population and isolate African Americans from the wider community.

Laws also shape social capital, social cohesion, and socioeconomic status in ways that can increase the risk of ill health and HIV risk. At current rates of incarceration, some estimate that 30% of African American men will soon be unable to vote because of laws that disenfranchise those convicted of felonies. Voting is a powerful measure of social participation that predicts involvement in other community-building activities. Depriving a substantial portion of a community of the right to vote not only decreases its ability to directly affect the outcome of elections, but it also decreases the overall social capital of the community. Incarceration also decreases social cohesion where substantial numbers of families have a parent in prison or where incarceration has greatly decreased the overall number of adults in a community available to act as role models or to supervise children.

Yet, structural interventions, including laws, can also be employed to decrease HIV risk. Several policy options are available that could potentially alter the role of law as a pathway for

social determinants (e.g., by increasing access to methadone and comprehensive HIV care). Laws can also seek to change underlying social determinants such as poverty, race, and community social organization.

Law may also be limited as a structural intervention. Whether and how laws are implemented and enforced may vary. For instance, some behaviors may be so intimate that law is a poor tool for change. Historically, laws aimed at adultery, sodomy, and fornication have been relatively ineffective in abating the behaviors. Other limitations include the fact that policy makers often find competing policy priorities and scientists and lawyers often find themselves speaking different languages. Nevertheless, law can profoundly shape social determinants. HIV-related laws represent one approach to integrating law and social epidemiology. Policymakers should consider additional research, reform, or intervention as they continue to refine responses to HIV and other health issues.

Conclusion

The process of passing public health laws regarding sexually transmitted diseases provides a vivid example of barriers often arising from consideration of previously unspoken sexual practices. A specific law may produce unforeseen or unwanted results. For example, new STD and HIV laws affect the workloads of healthcare employees who provide testing, referrals, and counseling. As a consequence, staff retention and data management, in particular, can be severely affected. At the same time, while new laws for improvements in HIV testing behavior hold promise, it is difficult to assess whether such laws cause the desired or even the observed changes. Finally, it is necessary to recognize that law is a structural factor influencing various social determinants and affecting health impacts in a broad sense.

Endnotes

a. This number ($124 million) includes figures for complications and hospitalizations due to pelvic inflammatory disease, chlamydia, and gonorrhea.

b. Any pregnant woman, neonate, person newly diagnosed with HIV infection, or person with infectious (primary or secondary) syphilis is considered a high priority client.

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Graduated Licensing for Teens: Why Everybody's Doing It

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ABSTRACT

While the United States traditionally has allowed quick and easy paths to full-privilege licensure of drivers at an early age, graduated licensing is becoming increasingly popular. The graduated licensing system phases in unrestricted driving by allowing beginners to get their initial behind-the-wheel experiences under conditions that reduce the risk of collision. As of June 2002, 35 states and the District of Columbia had enacted some sort of graduated licensing law. Recent evaluations of graduated licensing systems in four states have found reductions in crashes among 16-year-old drivers ranging from 11 to 33 percent. Yet, not all states have such laws, and many of the graduated licensing systems in use lack important provisions, such as nighttime driving and passenger restrictions. This article reviews the rules, restrictions, and provisions of the graduated licensing model; discusses evaluations of graduated licensing systems; identifies and analyzes variations in graduated licensing approaches across states; assesses the successes and failures of early graduated licensing laws, using New Mexico as an example; and discusses the potential of these systems to prevent injuries.

Motor vehicle-related injuries are the biggest health threat for teenagers in the United States, accounting for two out of five deaths in this age group. In 2000, more than 5,600 teenagers died in motor vehicle crashes, amounting to one every 91 minutes on the nation's roadways. Furthermore, the risk for motor vehicle crash deaths is higher among 16- to 19-year-olds than for any other age group. In fact, per mile driven, a 16-year-old driver is seven times more likely to crash than a driver 25 to 29 years old and is four times more likely to crash per mile driven than a driver age 65 or older. In 2000, the economic cost of both fatal and nonfatal police-reported crashes involving drivers ages 15 to 20 was $32.8 billion. The risk of crash involvement is highest for 16-year-olds, who have a more pronounced combination of immaturity and limited driving experience.[1–4]

Until recently, most states have allowed teens to get full-privilege driving licenses at an earlier age than in most other countries, typically requiring little prior driving experience. Graduated licensing, the key legislative issue for teen drivers in the U.S., is one approach to addressing preventable deaths. The combination of the high rate of driver deaths in the teen age group and the availability of the legislation makes graduated licensing a powerful instrument for reducing this major public health problem for teens.

The Need for and Adoption of Graduated Licensing in States

Data show that teenagers have more crashes per million drivers than any other age group. Data from 1995 show that males slightly outpaced females in crash risks among licensed drivers for all ages. An

examination of crash data by month of licensure for 16- and 17-year-old license holders reveals that the first few months of driving had very high crash rates; as drivers matriculated to 18 or more months of licensure, crash rates dropped considerably.[5]

Time behind the wheel is not the only risk factor, however. Another factor is that teens have difficulty with night driving. Drivers aged 16 and 17 years accumulate 14% of their miles but 39% of their fatal crashes between 9 p.m. and 6:00 a.m. The nighttime fatal driving experience for these drivers is much higher than for any other age group. An additional risk factor is the presence of passengers in the car with the teen driver. Unless the passenger is a supervising adult (age 21 or more years), the presence of passengers is a distraction for young drivers.

Graduating licensing legislation is an effective means of addressing the high crash and death rates among teenaged drivers. The principles of graduated licensing legislation are simple:

1. Keeping young, beginning drivers out of high-risk driving situations for which their coping skills are minimal;
2. Requiring low risk on-the-road practice driving;
3. Recognizing appropriate trade-offs between safety for the teen driver, passengers and others sharing the road, and the mobility afforded by teenaged driving; and
4. Granting teenagers full driving privileges only after completing a learner's stage (supervised driving only) and an intermediate stage (unsupervised driving in low-risk situations.

As of June 2002, 46 states have adopted at least one key element of graduated licensing legislation (GDL). Thirty-five states have both learner and intermediate stages of GDL. Nineteen states restrict the number of passengers who can be in the car with a licensed teenager. Thirty-six states restrict nighttime driving for licensed teens.

The Insurance Institute for Highway Safety has rated nine states as having "good" GDL laws. The criteria for the "good" rating include incorporation of a learner's phase of at least six months; an intermediate phase that includes either a nighttime driving restriction beginning at no later than 10 p.m. or a passenger restriction allowing no more than one passenger; and a minimum eligibility for full licensure of age 17.

Evaluations of graduated licensing programs are showing positive results. For example, North Carolina and Michigan, with GDL laws for 16-year-olds, have seen crash reductions of 29% and 27%, respectively. Ohio, which has GDL laws covering 16- and 17-year-olds, has seen a 23% crash reduction.

An Example of a State's Efforts to Pass a Graduated Drivers Licensing Law: the New Mexico Experience

New Mexico is a large, rural, sparsely populated state, geographically the fourth largest in the United States. The vast distances between points and the rural nature have resulted in the state's having many roads with 75 mph speed limits and an utter dependence on the car. There is a rural tradition of children who drive tractors at age 12 or even younger, a precursor of regular driving at a young age. New Mexico has one of the lowest driving ages in the country—15 years old. A teen can actually start training when 14.5 years of age.

The state also has the second highest driving fatality rate for teenagers in the country, with a teenager in New Mexico being 76 percent more likely to be killed in a crash than teens in the rest of the nation. In 1997, a teenager was killed in a traffic crash every seven days, and one was injured every 103 minutes. Before the 2000 New Mexico graduated licensing law was passed, the requirement for a driving license with full privileges was only 33 hours of classroom instruction, seven hours of behind-the-wheel instruction, and passage of a test.

There was a clear need for a GDL in New Mexico. However, prior to 2000, attempts to increase the age for full driving privileges had failed. The Western sense of individualism and personal rights often arose in the legislature to beat

down seatbelt requirements, driving under the influence (DUI) reforms, and mandates of all kinds. The state's governor had vetoed 750 pieces of legislation over a period of eight years as part of his commitment to limit the role of government.

Nevertheless, in 2000 New Mexico enacted a strong GDL program that incorporated a three-stage program, wherein 15-year-olds first get an instructional permit requiring 50 hours of behind-the-wheel experience (ten hours at night) taught by licensed adult. This phase lasts a minimum of six months. If this program is completed successfully, the teen gets a probationary license for one year with such restrictions as no driving between midnight and 5 a.m. and no more than one other teen passenger.

Supporters of the measure managed to gain passage by taking several steps. First, they ran a coordinated public relations campaign, using grassroots organizing, media relations, and citizen lobbying. It was a classic public relations (PR) campaign that in 2000 won a national award of excellence from the National Public Relations Society of America. The campaign used plain English to translate the results of research into crashes and fatalities of teenaged drivers.

In addition, supporters gained the help of both the state and the national offices of the American Automobile Association (AAA). Beginning in June 1998, supporters set the strategy after sifting through national and state research on traffic accidents, including local crash statistics, with AAA, the Traffic Safety Bureau, parents, and Mothers Against Drunk Driving (MADD).

Supporters also used the results of safety questionnaires sent to candidates to identify potential friends of the legislation in the state legislature.

After drafting the bill, supporters organized a dream coalition and started a statewide database of organizations and individuals who might support this measure. From the very start, supporters knew that they had to contact the families of victims and get them to write letters and make media appearances. The supporters also identified opponents as well as stakeholders and persons who would have to implement the program. The strategy was to start making presentations to driving schools, parent organizations, public safety workers, and other possible partners. And the supporters got input from teenagers themselves before preparing a final draft, a means of developing in these teens a sense of ownership in the bill.

Likely allies included child safety proponents, physicians, parent teacher associations (PTAs), the AAA, MADD, and emergency medical technicians. Other strong partners not initially identified proved to be the police and sheriff departments, Anheuser Busch, the Beer Institute, insurance companies, and fire departments. One key lesson learned during the campaign was that the media can be a friend. Every newspaper in the state editorialized in favor of the legislation, and the draft bill became the subject of major TV news features.

The final outcome was a vote in the New Mexico State House of 60 to 0 in favor of the bill, and in the Senate it was 29 to 7. The law is now in force. It is a victory for public health.

Although it is too early to indicate precisely how successful the program has been, preliminary data from the University of New Mexico's Division of Government Research indicate a seven percent decline in fatal and nonfatal injury crashes among 16-year-olds—a percentage that translates to 68 teenagers.

Conclusion

Statistics clearly point to the hazards of providing full licensure to teenaged drivers. Graduated licensing laws provide states with a way of reducing the injuries and deaths occurring among this driver group. Evaluations of existing GDL laws are already showing their effectiveness, although continuing analysis of data is important. While the process of gaining passage of GDL legislation in a state can be difficult and arduous, the development of a sound strategy involving conducting a sound public relations campaign and forming effective coalitions can provide a foundation for the success of GDL supporters.

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Kids in Cars: Closing Gaps in Child Occupant Restraint Laws

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ABSTRACT

This article provides background on the latest research and findings related to child occupant restraint laws; highlights recent and proposed legislation mandating child occupant restraints, along with strategies and partnerships leading to the adoption of the legislation; and identifies practical steps that elected officials and public health practitioners can take to adapt and replicate those strategies and policies in their states and communities.

Motor vehicle crashes are the leading cause of death for children ages fourteen and under in the United States. About 2,300 children this age died in motor vehicle crashes in 2000.[1] Of those who died as occupants in traffic crashes, only 44 percent were wearing a seat belt or using a child safety seat.[1] The fact remains that while all 50 states have some sort of occupant restraint law to protect children, those laws vary dramatically, and most have serious gaps in coverage. Studies show that when properly used, child safety seats can reduce fatal injuries by up to 71 percent for infants and by 54 percent for toddlers.[2] The use of seat belts reduces fatal injuries by at least 45 percent. Over half the children killed each year in motor vehicle crashes would be alive today if seat belt and child safety seat use were at 100 percent.[1] This kind of use can only be accomplished with comprehensive laws, active enforcement, and public health awareness campaigns. According to a Harris poll, 90 percent of the public favors stronger enforcement of laws that require all children to be buckled up.[3] The majority of children killed in motor vehicle crashes are completely unrestrained. Many of these deaths are preventable. Proven, effective interventions exist to address child occupant safety, including the use of child safety seats. Laws are also an effective way to protect children. A systematic review of the scientific literature by the Guide to Community Preventive Services Task Force found that child safety seat use laws were effective interventions, and this task force has strongly recommended passage and enforcement of such laws.[4] In combination, child safety seats and legislation are powerful tools for protecting children. The sections that follow discuss examples of initiatives designed to promote passage of child passenger legislation, one at a national and two at a state level.

The National SAFE KIDS Initiative to Improve Child Restraint Laws

In early 2001, the National SAFE KIDS Campaign released a study that rated child occupant protection laws in all 50 states and the District of Columbia.[5] The study was predicated on the understanding that while state child restraint laws tell parents how to restrain their children legally, these laws do not necessarily reflect the safest way for children to ride in motor vehicles. A strong law that is well enforced and addresses both nonuse and misuse of child restraints is critical. Knowing that parents often look to the law for guidance and that motor

vehicle crashes remain the leading cause of unintentional injury-related death for children, SAFE KIDS graded the states' existing child passenger safety laws and launched a five-year advocacy initiative to strengthen them.

SAFE KIDS measured the states' child restraint laws against a model law that requires correct restraint of all children, in all seating positions, in the care of all drivers. Stringent standards were used to assess each state's law because any gaps in coverage could lead to serious or even fatal injuries for children. States were graded according to whether their laws contained

1. a requirement of restraint use through age 15;
2. an age-appropriate child restraint requirement by age;
3. a proper child safety seat adjustment clause;
4. a public education/public fund component to promote child passenger safety;
5. appropriate penalty provisions for violations of the law;
6. inappropriate driver/circumstance exemptions from the law; and
7. other, miscellaneous provisions.

SAFE KIDS based its rating system on a 100-point scale. Grades A through F were assigned to a state's law according to a standard academic grading system. Each grade was based solely on the language of each law, not on its implementation or enforcement. The only assumption was that a good law is the cornerstone of any state's commitment to child passenger safety. As a result of the ratings, SAFE KIDS confirmed what many safety advocates already knew: startling gaps existed in coverage related to age, seating position, and the lack of specific guidelines for child safety seat use.

Nearly half of all the states earned Fs for laws that failed to properly protect child passengers, and more than one-third of all states and the District of Columbia earned Ds. Seven states earned Cs. One state earned a B, and only one state earned an A. Surprisingly, 34 states allowed child passengers to ride completely unrestrained in certain circumstances. The exemptions permitting unrestrained child passengers included those for nursing mothers, for automobiles with out-of-state license plates, for non-state resident drivers, and for overcrowded cars. According to some state laws, a child could ride unrestrained merely because other passengers are occupying all other seating positions and using the accompanying restraints. Thus, in situations such as a carpool, children did not have to be buckled up in the absence of enough safety belts. Such loopholes in child passenger safety laws not only confuse parents regarding the applicability of the laws, but also serve as a disincentive to law enforcement. Exemptions from child restraint requirements both weaken the law and deprive police officers of a clear mandate to keep kids safe.

These failing grades also reflected the fact that in many states, at the time of the study, children are legally allowed to ride completely unrestrained in the back seat of a vehicle, while other states allowed very young children to use adult safety belts. For instance, in Idaho, Ohio, and Pennsylvania, children ages 4–8 could ride completely unrestrained in the back seat—putting them in a potentially dangerous situation. In New Mexico, children as young as age two could be restrained by use of an adult safety belt alone. And in New Jersey, children who were 18 months old could legally ride in a back seat restrained only by an adult seat belt. Overall, SAFE KIDS concluded that no state fully protected all its child passengers ages 15 and under, including the state that earned an A. Specifically, no state required children ages 6–8 to ride in an appropriate restraint, such as booster seats.

The good news, however, was that all 50 states and the District of Columbia have passed laws that require at least some children to ride restrained, even if those laws vary widely in their age requirements, exemptions, enforcement procedures, and penalties. California earned an A for passing a strong child restraint law in 2000. In addition to meeting almost all other rating criteria, the California law specifies the use of age- and size-appropriate restraints for children ages 5 and

under. California's law also contains other outstanding provisions, including (a) providing for a public education campaign that includes information about correctly installing a child safety seat; (b) establishing a public fund to assist economically disadvantaged families in obtaining child restraints; (c) setting up a child safety seat loaner program; (d) providing an option for low income parents convicted of violating the restraint law to attend a child passenger safety class in lieu of paying monetary fines; and (e) requiring car rental agencies to inform their customers about the state's child occupant protection law.

As part of Child Passenger Safety Week 2001, SAFE KIDS launched a five-year advocacy initiative aimed at closing the gaps in and strengthening child restraint laws. After all, the failing grades in nearly half the states had demonstrated that child safety needs to be a higher priority for state legislators, governors, and citizens. Working in partnership with the nationwide network of 300 SAFE KIDS coalitions, SAFE KIDS developed an initiative that seeks to

1. identify and create awareness of the gaps and weaknesses in state child restraint laws;
2. advocate stronger laws;
3. educate families about how to restrain their children in motor vehicles properly and highlight the difference between best practices and their states' laws;
4. develop and execute a strategy for passing improved laws that are based on the SAFE KIDS model child restraint use law,
5. assist states in their law enforcement efforts by generating public support for strong enforcement of child restraint laws; and
6. provide police officers with educational tools to teach them about the provisions of their own state child restraint laws.

The goal of the initiative is passage and enforcement of upgrades of child restraint laws in all states by 2006.

Since the report was released, at least 30 states introduced legislation in 2002 to improve their child restraint laws—many the result of grassroots advocacy efforts of SAFE KIDS coalitions. Seventeen states and the District of Columbia passed new laws in 2001 and 2002: Arkansas, Georgia, Illinois, New Jersey, New Mexico, Oregon, Rhode Island, South Carolina, Tennessee, Texas, Colorado, Delaware, Maine, Maryland, Nebraska, Oklahoma, and Virginia. Eleven of those states (Arkansas, Colorado, Delaware, Maine, Maryland, Nebraska, New Jersey, Oregon, Rhode Island, South Carolina, Virginia, and Michigan) went one step further by joining California and Washington as the only states to mandate booster seat coverage for some older children. New Jersey's is the most comprehensive of those requiring the use of child safety seats or booster seats in terms of age coverage: it requires children ages 7 and under and weighing less than 80 pounds to use appropriate child safety seats or booster seats.

The National SAFE KIDS Campaign's website, located at <www.safekids.org>, provides a summary of each state's child restraint law as well as the *Rate the States* report.

A State-Level Initiative to Enact an Effective Child Restraint Law

The ultimate responsibility of government is to provide for and protect its children to enable them to prepare for the future. Colorado's 2001 experience in closing loopholes in its existing child passenger restraint law illustrates carrying out that responsibility. The effort exemplifies the use of coalitions and legislative acumen to bring about reform.

Brief research of existing child safety seat laws showed that Colorado did not require child passengers to use booster seats. National statistics showed that booster seats in motor vehicles are the safest way to protect most children, including at the age of 4 through 8. The data showed that children ages 4–8 wearing adult seat belts are over three times more likely to sustain significant injuries in a crash—especially head injuries—than children in booster seats. In addition, the data showed that:

1. motor vehicles crashes are the leading cause of death for children through age 14;
2. motor vehicle crashes are the leading cause of death among Hispanics through age 24; and
3. motor vehicle crashes are the leading cause of death for African Americans through the age of 14; the risk of a fatal crash for African American children ages 5–12 is almost three times greater than for white children.

In Colorado in 2000, the Children's Hospital admitted 35 children ages 4–8 who were involved in motor vehicle crashes. None of these patients were using booster seats: 17 were restrained with seat belts (4 in lap/shoulder belts, 13 in lap belts only), and all these showed signs of seat belt injury; 18 were unrestrained, two of whom died from injuries suffered in the accidents. In Colorado, 10 of the 34 children killed in car accidents in 2000 were booster seat-sized and not restrained by booster seats.

Research of the Colorado revised statutes done by Denver's Children's Hospital revealed a loophole in the existing Colorado child passenger restraint law. True, Colorado had made the decision to protect automobile passengers by requiring that all passengers in motor vehicles use seat belts (with the exception of infants, who were required to be in child car seats). The problem, the loophole, was that while the statute specified that everyone in a motor vehicle must be restrained and children under 4 years of age and weighing less than 40 pounds must be properly restrained in a child safety seat, the previous law stopped there. The law provided that children beyond the age of 4 years could be restrained only by a seat belt. This provision tended to give parents a false sense of security that their children were entirely safe in the event of an automobile accident.

The introduction of House Bill 1070 (HB 1070) was the beginning of an effort to close that loophole. This bill specified that child passengers of booster seat size up to age 8 were to be restrained by booster seats. The existence of a conservative chamber that tended to frown upon growth of government and the perceived interference of government in the exercise of individual liberties helped to ensure that opposition to the bill would be intense. Passing the bill would require use of a four-part strategy: (a) win the war of words and perception; (b) win the arithmetic game in terms of vote count; (c) show widespread public support for the bill; and (d) show that the national trend was toward state adoption of laws mandating the use of child safety and booster seats.

The war of words and perception focused on the terms *loophole*, *safety*, and *children* as a means of overcoming opposition that was based on the assumption that the bill would enhance government growth and government interference in individual lives. Supporters of HB 1070 portrayed it as closing a loophole in an existing law, not necessarily as representing a new law *per se*. The second part of the war of words and perception was to agree for argument's sake that HB 1070 was an extension of government and that it might represent government interference or inconvenience for individuals, but that the safety of the children outweighs that exercise of government control. Finally, proponents of the bill emphasized the fact that it was designed to protect children; it was not focused on actions specific to adults.

Winning the arithmetic game required proponents of the bill to recognize some practical realities in the legislature. In all, the Colorado general assembly has 100 members—65 in the House and 35 in the Senate. The numbers game in Colorado public policy could be summarized as 33-18-1—the bill's proponents needed 33 votes to pass the bill in the House, 18 in the Senate, and the signature of the governor. For a Democrat, getting 33 votes in the House would not be easy. Since there were only 27 Democrats, the bill's supporters needed the votes of 6 Republicans. The focus of the actions of the bill's supporters was therefore to curry support from moderate Republicans at each step in the legislative process—in committee meetings as well as on the floor.

The strategy to show widespread public support for the bill assisted proponents in gaining support from the moderate Republicans. The bill's supporters would need the crucial help of partnerships

consisting of external groups as well as testimony from compelling witnesses to demonstrate that public support. Seven important groups signed on early in this effort: the Children's Hospital, State Farm Insurance, the Colorado State Patrol, the American Automobile Association, the Denver Metro SAFE KIDS coalition, the Colorado Health and Hospitals Association, and the Junior League of Denver. In addition, parents from across the state who attended a kids expo signed 250 letters of support for the bill. The bill's proponents gained persuasive testimony in committee hearings from several individuals.

Finally, the bill's proponents had to show that protecting children with a law mandating use of child safety seats was not an aberration, but a growing national trend. In each committee hearing and during the floor debate, some legislator would ask how many other states had taken similar action. The reply at the time was that seven states had passed booster seat legislation.

The strategy worked. On April 9th, the House passed the bill 36-28-1. The bill passed the Senate 21 days later with 20 votes, and the governor signed it on June 4.

The final bill was an acceptable compromise. The bill consists of three specific parts:

1. it provides that if a child is less than a year of age and weighs less than 20 pounds, the child must be rear-facing;
2. if the child is one year old but less than 4 years old and weighs less than 40 pounds, the child must be forward-facing; and
3. if the child is between 4 and 6 years old and less than 55 inches in height, the child must be in a booster seat, and if the child is between 6 and 16 years old and 55" or more in height, the child must be restrained by a seat belt.

Violations are a secondary offense. The act provides a one-year period during which violators receive a warning, but no ticket. The effective date for full enforcement of the law is August 1, 2003.

Although the bill has become law, an extensive and aggressive public education campaign to be implemented by Children's Hospital awaits completion over the next year. This campaign will include public service announcements made by local media (a fact flyer has already been sent) and highway message signs. In addition, the Colorado Department of Transportation has undertaken a highly publicized "click it or ticket" campaign to encourage people to use their seat belts. The public education campaign will also be working with 350 trained carseat specialists across Colorado to assist parents in installation of child safety and booster seats. Finally, the campaign will enlist the help of a partnership of 1,700 child advocate agencies across the state as well as the help of statewide county human services and health departments.

The Use of Coalitions and Policy Approaches to Promote Child Passenger Safety: Another State's Experience

Rhode Island has a long history of legislative success in protecting its youngest citizens as they travel the state in cars. In 1981, it became the second state to enact child passenger safety legislation. This legislation covered children through age 4. In 1987, the laws were amended to mandate seatbelt use for children ages 4 through 12 years for seat belt use, and violations became primary offenses. In 1997, the state amended the laws to require children up to age 6 be restrained as back seat passengers. And in 2001, an amendment required that children up to age 7 who weighed 80 pounds or less and were 54 inches or less in height be restrained in back seats. Rhode Island was the sixth state to enact a booster seat use law. Strangely, Rhode Island was only the 40th state to pass an adult seat belt law, a toothless piece of legislation that included no fine for not using a seat belt. Later, in 1999, however, that law was amended to provide for a $30 fine, and in 2000, the fine became $50 as a result of passage of a uniform fine act.

In 1997, the momentum behind passage of highway safety legislation increased dramatically

when the governor established the Rhode Island Traffic Safety Coalition, a broad-based group chaired by the state's Director of Transportation. The Rhode Island Department of Health (HEALTH), through its legislative liaison and its Injury Prevention Program, has been an active member of this coalition since the coalition's beginning. Other members of the coalition are

1. representatives of other state government agencies, including the courts, the state police, and the attorney general;
2. representatives from the National Highway and Transportation Safety Administration and the Federal Highway Administration;
3. state legislators;
4. insurers;
5. the Automobile Association of America;
6. statewide voluntary organizations such as Mothers Against Drunk Driving, SAFE KIDS, the Brain Injury Association, and AARP;
7. health care providers and researchers; and
8. local police departments.

The coalition's mission includes promoting traffic safety for all age groups. Its focus is not confined to legislation. It meets quarterly and sets an annual legislative agenda of five to six bills. Since 1998, two to three of those agenda items have been enacted every year.[6]

Although no child passenger legislation was passed in 1998, two key measures protecting children were enacted during that year: graduated licensing for teen drivers and bike helmet requirements for children 15 and under.

In 1999, Rhode Island passed a measure that doubled the fines for DWI when there are children under 13 in the car. In 2000, the coalition supported passage of a law lowering the blood-alcohol threshold for drunk driving to 0.08. And in 2001, in addition to extending the helmet requirement to skateboard and in-line skate users, Rhode Island upgraded the child restraint law to mandate booster seat use for young children.

Rhode Island Public Law 121, passed in 2002, updates the language of the child restraint laws to define rear seating more specifically. This action recognized the fact that vehicles such as vans and sport utility vehicles may have more than one back seat and that children should be restrained in the usually safer middle row of rear seats in such circumstances.

As the primary vehicle to move legislation in recent years, the coalition has counted on the following strategies to advocate the adoption of stronger Rhode Island child restraint laws:

1. Focusing on key leadership from the Governor's Office on Highway Safety and from the Director of Transportation, who speaks passionately and acts similarly regarding highway safety issues;
2. Securing endorsements of proposed legislation from a broad-based and diverse group.
3. Focusing on a broader highway safety package that places priority on passenger restraints and includes amendments to drunk driving statutes; and
4. Using articulate bill sponsors and providing witnesses who furnish effective testimony in support of bills.

Inherent in these strategies is recognition of the fact that policy approaches are ineffective unless they recognize that (a) child safety cannot be taken out of the context of traffic safety laws for all ages, and (b) parental role models have great influence, and parents who routinely do not buckle up (a more likely occurrence without a strong primary seat belt law) are likely to raise children who do not buckle up either. Nationwide observational research[7] shows that when a driver is buckled, restraint use for children (0–15) is 86.9%; and when a driver is unbuckled, restraint use for children (0–15) is 23.7%.

As in many other states, success in the Rhode Island Legislature to secure effective child restraint action has not been easily won. Throughout the process of passing passenger safety legislation, legislators have been concerned about a number of issues, including the issue of "punishing" parents, the viability of enforcement

of the height and weight requirements, and other obstacles to enforcement These arguments have been successfully countered with strong testimony about the importance of these laws as an educational tool for law enforcement officials and safety advocates.

Finally, enforcement is a crucial component to ensure the effectiveness of passenger restraint laws. The effectiveness of the "click it or ticket" enforcement program held throughout the country during the 2002 Memorial Day holiday demonstrates that education about and enforcement of these laws is a winning combination. In addition, employing a strategy that includes the police departments as active members of a supporting coalition can increase the attention to enforcement.

Conclusion

Many of the deaths and injuries of children as well as adults in automobile accidents are preventable, given passage and enforcement of appropriate passenger restraint laws. Closing loopholes in existing restraint laws should be a priority in state efforts. Closing these loopholes requires supporters to promote education about the effectiveness of sound child restraint laws, to form statewide coalitions that will demonstrate wide public support and provide effective testimony, and to recognize that child safety laws must exist within the broader context of passenger safety requirements. Finally, effective enforcement of strengthened laws is crucial. It can be gained by drafting clear, comprehensive laws that eliminate loopholes and exceptions, by educating law enforcement personnel about the provisions of such laws, and by including law enforcement agencies in coalitions that support passage of strengthened passenger restraint laws.

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Violence Against Women: the State of Batterer Prevention Programs

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ABSTRACT

While both men and women can be victims, domestic violence usually consists of assaults on women, and most violence against women occurs within an intimate relationship. In the past twenty years, numerous state and provincial programs to intervene in domestic violence cases have developed. The programs tend to focus on treating batterers, although they also offer counseling to domestic violence victims. The jury remains out on the effectiveness of these programs. A major issue is whether the programs use appropriate standards. After an overview of the prevalence and nature of domestic violence, this article provides a discussion of those standards—their nature, effectiveness, and limitations. Another section discusses use of a batterer intervention program in an urban setting. Yet another section explores the implications of intimate partner violence and looks again at the effectiveness of batterer treatment within intervention programs. The article closes with a look at the way one state addresses domestic violence and treats it as a crime. An inescapable conclusion to be drawn from the discussion is that violence against women has its roots in cultural assumptions that must undergo change if the incidence of that violence is to be reduced.

Approximately 2.1 million women are physically assaulted and/or raped every year in the United States. Of these assaults or rapes, 1.5 million are perpetrated by intimate partners: current or former spouses, boyfriends, or girlfriends, including heterosexual or same-sex partners.[1] Regrettably, women are victimized by their intimate partners repeatedly. Women who are physically assaulted by an intimate partner report an average of 3.4 assaults every year, while those who are raped report an average of 1.6 sexual assaults every year. In all, intimate partners perpetrate approximately 4.8 million physical and/or sexual assaults annually.

Women are not the exclusive victims of intimate partner violence (IPV): 834,700 men are physically assaulted and/or raped by intimate partners in the United States every year. However, not only is the rate of victimization among men significantly lower than among women, but the differences between women's and men's rates of physical and/or sexual assault victimization become greater as the severity of assault increases.[1] For example, women were two to three times more likely than men to report that they had been pushed, shoved, or grabbed. However, women were seven to fourteen times more likely to report that intimate partners had beaten them up, choked them, threatened or actually assaulted them with weapons, or attempted to drown them.[2] As a consequence of severe intimate partner violence (IPV), women are more likely than men to require medical attention, to take time off from work, and to spend more days in bed as a result of their victimization. The psychological consequences for victims of IPV include depression, suicidal thoughts and attempts, lowered self-esteem, alcohol and

substance abuse, and post-traumatic stress disorder.[3] Women who are experiencing ongoing IPV report deteriorating physical and emotional health over time.[4] Nonlethal IPV has been conservatively estimated to result in financial losses of approximately $150 million per year.[5] Medical expenses accounted for approximately 40% of these costs, property loss for another 44%, and lost pay for the remainder.

Although women are the primary and direct victims of IPV, children of battered women suffer similar consequences. Each year, more than ten million children witness IPV within their families, and witnessing violence has been shown to increase the risk for the development of acute and long-term physical and emotional health problems.[6,7] Further, violence against women by an intimate partner is a significant risk factor for child abuse.[8,9]

The high prevalence, incidence, and consequences and costs of intimate partner violence have galvanized various disciplines to develop programs to help victims recover from abuse and live abuse-free lives. However, equally important is the prevention of violence against women. Interventions targeting perpetrators and would-be perpetrators are key in the prevention of violence against women. To this end, male batterers are frequently mandated to participate in treatment programs to reduce future battering. State laws may certify specific programs that batterers must attend in order to have completed their mandated treatment. But research evidence suggests that there may not be significant differences in the outcomes among available treatment programs. Further, some research suggests that different types of batterers may respond differently to existing programs. Accordingly, it is not clear that all batterers should be mandated to the same type of treatment program or that some programs should be excluded from the pool of potentially helpful interventions.

This article reviews scientific data on the effectiveness of batterer intervention programs and discusses the legal and policy implications of those data. It also attempts to provide answers to certain questions. Have specific programs been shown to be effective or ineffective? What dimensions of programs are related to program effectiveness? Are certain kinds of programs more effective for certain individuals? What is the current status of state-certified programs? On what basis do states certify programs? What do the data suggest about the dimensions upon which states should certify programs? What is the relationship among scientific research, advocacy, and policy related to programs for batterers?

An Analysis of Standards in Batterer Intervention and Prevention Programs

Two national surveys and analyses of standards for batterer intervention and prevention programs conducted by Juergen Dankwort and Juliet Austin exist. The surveys were produced and administered under a contract with the U.S.-based National Resource Center on Domestic Violence, a project of the Pennsylvania Coalition Against Domestic Violence, with additional funding from the Office of Community Projects, University of Houston. These surveys examine the standards that exist in the United States and Canada to regulate the practice of working with domestic violence offenders—perpetrators of domestic violence. An explosion of programs to address domestic violence over the last two decades has occurred. With that explosion have come growing concerns about what is being done with the offenders. The source of many of the expressed concerns has been advocates who work with the victims of domestic violence.[10–12]

The history and development of standards used in the various domestic violence programs to treat batterers are generally uniform. In the United States, committees comprised of battered women's advocates, facilitators of batterer programs, criminal justice personnel, and mental health professionals developed standards or guidelines in the 1980s. State domestic violence coalitions driven by strong feminist ideology often played a central role in the development process. Many of these standards are relatively

similar, with those developed in one state often having served as models for other states. The rationale in support of the standards was generally identified as a need to maximize safety for domestic violence victims in view of rapidly proliferating batterers' programs with varying, and, in some cases, divergent approaches to batterer treatment interventions.

In Canada, the development of standards emerged in the late 1980s through initiatives jointly undertaken by counselors of batterers' programs and representatives of provincial governments, with some variance by virtue of the additional involvement of other interested parties. These standards were developed through designated committees. The rationale for the Canadian development of standards was identified as a need for accessibility and accountability of programs that entered into contractual agreements with government funding agencies and the need for program uniformity, improved coordination with collateral domestic violence services, and victim safety.

Two basic categories of standards exist: (a) mandatory standards, with and without accompanying legislation; and (b) voluntary standards, some of which are adhered to by many programs and others of which are not commonly referenced because there is little inducement for program compliance with them. Programs are required to commit to following mandatory standards as a condition of being funded and licensed to operate. On the other hand, while programs are not obligated to adhere to voluntary standards, voluntary standards in some cases seem to be followed more often than mandatory standards, perhaps because particular voluntary standards may be very well known. It is important to note, however, that the fact that some standards are mandatory does not ensure that they will always be followed in practice.

In the United States as of 1997, 17 states had mandatory standards for domestic violence intervention programs for offenders, 12 states had voluntary standards, 8 states had standards in a draft stage, and 11 states had standards in development. In Canada, just over half of the provinces and territories had such guidelines in place, several of which were obligatory for programs to follow as a condition of funding. As of 1997, only 3 states (Mississippi, Arkansas, and Idaho), 5 Canadian provinces, and 1 Canadian territory had not yet begun to develop standards.

To obtain their data for the two national surveys and analyses concerning domestic violence program standards, Dankwort and Austin used telephone surveys of domestic violence coalitions and other organizations. After collecting the information and analyzing it, they created categories. For purposes of analysis, the elements of standards were summarized in seven broad categories and then broken down into identified themes within these categories. The broad categories include: (a) Philosophy of Standards; (b) Purpose and Procedures of Standards; (c) Protocol for Programs; (d) Staff Ethics and Qualifications; (e) Intake Procedures; (f) Intervention: Format, Mode Content, and Duration; and (g) Discharge Criteria. The elements do not necessarily reflect the contents of an actual standard, but instead are categories created to organize the information collected. For example, a theme within Philosophy of Standards is "Patriarchy", seen as causing and/or maintaining men's violence against women. "Abuse" is conceptualized as the use of coercive control over anoter, socially reinforced through sexist attitudes, etc. The category of staff ethics and qualifications incorporates some requirements that program facilitators must be violence free, must not abuse alcohol or drugs, must seek to rid themselves of sexist attitudes, and should have training specifically in domestic violence issues.

The findings of this research provided information about the contributions and limitations of batterer program standards. Additionally, the research made it possible to identify the concerns that preoccupy some key participants and stakeholders who are engaged and invested in ending domestic violence. The research found that the contributions of standards in domestic violence program included (a) promotion of a

priority on victim safety and batterer accountability; (b) facilitation of a process by which those with varying interests and particular mandates can work together to end domestic violence; (c) promotion of consistency among programs and the existence of accountability to the community; (d) the existence of consumer education by virtue of publicizing the content of programs along with program limitations; (e) acknowledgement of expertise from victims' advocates; (f) encouragement of a coordinated community response to stopping domestic violence; (g) emphasis on the social dimensions of domestic violence; (h) exertion of influence for existing programs to develop new programs and facilitate the development of standards in other regions; and (i) legitimization of the need for specialized knowledge, training, and intervention approaches in relation to work with abusers.

The findings also revealed the limitations of existing standards. These limitations include the fact that (a) standards sometimes lack specificity or fail to explicate their rationale; (b) standards do not discuss how to intervene with gay men and lesbian offenders who have been charged with domestic violence; (c) mandatory standards may turn into a form of unwanted control if access to revise or modify them is lobbied away from grassroots interests; (d) compliance with standards is complex and may be problematic on various levels—for example, standards may obtain a superficial acquiescence without real commitment by practitioners to implement their underlying purpose, or there may be no action if the standards are not mandated; (e) standards may be infrequently monitored and/or unfunded; (f) standards may be inadequate if their only requirement is attendance by batterers of a required number of sessions in order to complete a program; and (g) standards may have been developed without researchers' input, without the inclusion of mental health professionals, without a scientific research basis, and without a requirement that batterers' counselors possess academic degrees or professional licenses, as some professionals and scholars in the mental health community in the United States have charged.

It is evident from this research that a significant trend to establish standards for batterers' programs is well underway in North America. The conclusions to be drawn from the research suggest future directions that standards might take as they come up for revision or as they are formulated for the first time in those regions where they are presently under development. Existing and developing standards might seek to address whether and how to develop standards for women mandated to attend a batterer's program; how to intervene with lesbian and gay male offenders; how to intervene with various cultural, ethnic, racial, and religious minority groups; how to address some of the divisive underlying controversies raised by the standards, including the matter of diversion intervention approaches and practice methods to address safety issues for victims; how to encourage the justice system to function in a manner more in accordance with the standards; how to develop effective economic ways to monitor program compliance; and how to encourage additional innovative research regarding program impact, the types of desirable curricula, intervention protocols, and the overall effectiveness/impact of standards.

These researchers have recommended that victim safety and batterer and program accountability be the deciding criteria by which any proposed changes to standards are measured. In the absence of conclusive scientific evidence to support the content of existing standards, programs should use knowledge based on experience acquired by the battered women's movement over more than two decades as a reliable foundation for intervention practices.

Batterer Intervention Programs: One State's Experience

Georgia is one of the states that do not have standards and thus no quality assurance for batterer intervention programs. However, in the 2002 session, the Georgia legislature passed legislation giving the commission the jurisdiction to develop such standards. As in many other states, the main rationale for developing standards is victim safety

and offender accountability. Standards will outline the minimum requirements as determined by existing national minimum standards.

Extensive solid research in the area of batterer intervention programs is nonexistent. Ed Gondolf[13] is one investigator who has engaged in some sound work. Still, the findings of existing research into batterer intervention programs remain inconclusive and controversial. One of the most controversial areas is whether batterer intervention programs fully address the root of the problem. Certainly it makes sense to standardize such programs if the bottom line is victim safety. However, communities find it hard to accept that batterer intervention programs are not always the answer. While it makes sense to have certification of the programs, it also important for communities to understand the limitations of batterer intervention programs. Part of the reason that intervention programs are not the ultimate answer is that the majority of men who assault women never enroll in those programs. A major issue is how to impact those men who normally do not become involved in intervention programs.

Looking at social structures and cultural norms as an important context in violence against women is critical. In twenty years of working with men who batter, the organization Men Stopping Violence has learned that batterers gain much of their direction about how to relate to women from their cultures. In essence, they learn from their cultures that it is permissible to abuse women. Men receive messages that abusing women is acceptable even from institutions such as churches and other faith communities as well as the judicial system. Hence, batterer intervention programs generally are only as good as the community in which they are functioning. Thanks to the battered women's movement, however, the message that violence against women is unacceptable is beginning to take root in a variety of cultures.

Part of the challenge of efforts to stop violence against women is making an accurate determination of whether victims and potential victims are really safe even after an intervention begins. In research, the only way of knowing is through partner reports, a limitation that researchers must recognize. After all, manipulation is one of the hallmarks of the way batterers relate in the classroom and in the system. While the physical abuse may stop, or the batterer may find creative ways not to enter into the judicial system, verbal assaults and threats can continue to keep the terror alive. The system is not measuring the looks, threats, or emotional assaults-it is merely looking for whether a victim has been assaulted physically. If it is true that victim reports are the only reliable way of knowing whether an intervention program is having an impact, then those data must be put into a broader context when obtained. Also of concern is that many victims' main interest is stopping the present abuse. These victims do not necessarily want to leave or damage the relationship in which the violence is occurring. A victim may modify her reporting, even for a researcher, if she is concerned that reporting the batterer may result in his having to reenter the system.

Batterer intervention programs must therefore be placed in a broader context, with their functions as well as their limitations acknowledged. Men Stopping Violence uses its batterer intervention program to leverage communities and to impact legislators and institutions. The program is really a conduit to communities, rather than the ultimate answer. At the halfway point of the 24-week Men Stopping Violence program, a batterer is required to bring in several members from his community, such as his pastor or boss, to witness the work done in the program so that these community members can, in turn, take the information back to the community. In the long run, communities must take responsibility for both the problem of violence against women and for developing the solutions to it.

Implications for Victims of Intimate Partner Violence

Batterer treatment programs for victims of intimate partner violence must be examined in

terms of safety and accountability. One study by Gondolf considered victims' perceptions at the time of entry of their batterers into batterer intervention programs of both short- and long-term duration. The findings indicated that within one week of men's program intake, 95% of victims believed their batterers would complete the program. In fact, the results of that study found that only about half the men actually did complete at least three months. Fifty-nine percent of victims said that the batterer had admitted a violence problem, but another analysis had found that there was really no relationship between admitting the problem of violence and the incidence of re-abuse. Sixty percent of victims said that they felt very safe, and 44% felt that they were unlikely to be assaulted again in the near future. After four years, 47% of the perpetrators had, in fact, re-abused at some point during that four-year period. Complicating the task of examining the re-abuse issue is that abuse may not have been inflicted on the same partner, but rather could have been inflicted on the same partner, on a new partner, or on both.[13]

A study by Heckert and Gondolf looked at predictors of the victims' perception of whether they found themselves to be at risk at the time their batterers entered programs. This study found that the best predictors of a victim's perception of high risk were based on the batterer's previous use of controlling behavior and his previous use of severe physical violence. Being married, not living together, and frequent episodes of the batterer's being high or drunk were also predictors.[14]

An extended follow up by Gondolf in 2001 looked at how victims perceive their situations after their batterers had completed domestic violence programs. Nearly two thirds of women reported being "better off" after 15, 30, and 48 months following batterer treatment; 85% felt "very safe" and "very unlikely" to be assaulted again at 30 months and 48 months following program treatment; and 12% reported that they felt "worse off." However, 25% of perpetrators repeatedly re-assaulted after program completion.[15]

In her study of women's perceptions of batterer treatment programs, Juliet Austin concluded that victims of perpetrators involved in domestic violence programs reported feeling safer, having enhanced well-being, feeling validated that the abuse was not their fault, and having acquired new knowledge about domestic violence—all positive outcomes of a batterer treatment involvement.[16]

Finally, an unpublished manuscript by Ferris on the effects of partner contacts by a batterer intervention program known as Emerge found that 86% of women said that they were satisfied with the program; 81% said they felt that their confidentiality was protected by the program; 25% said that the contact was their first opportunity to talk about domestic violence (this is critical, given that contact can maximize the ability to capitalize on the opportunity for intervention); 25% said that they felt influenced to end the relationship; 39% said that they felt influenced to seek help for themselves; 10% said that they were influenced to file a child abuse report; 55% said that they believed the program was effective; and 50% said that they experienced repercussions. Though repercussions did not always take the form of physical violence, in some proportion of the cases they did.[17] While these findings and others reflect a fairly optimistic overall view by victims, a significant factor for all women is that batterer treatment programs can result in repercussions and in a general worsening of situations for them.

In all, research findings have a number of implications. For example, batterer behavior must be monitored closely within the initial three months of entrance to a program. There must also be some provision for follow-up support and safety for victims. To some extent, the violence intervention field must grapple with the issue of how to address what appears to be a somewhat overly optimistic view about the effectiveness of batterer treatment. Certainly, some batterers do not re-offend; yet, the risk of batterers' re-offending must not be denied. In addition, it is very important to victims for programs to offer or refer victims to other services, despite the research

suggesting that most victims of batterer treatment program partners do not use other services and that victims report that they do not perceive the need for such services. Another safety issue is that victims should not be coerced into couples' treatments. In addition, victims' and advocates' voices must be included in the discussion about batterer treatment programs, given that they have the longest history with these issues. And as Gondolf suggests, batterer treatment programs need to make sure to incorporate new partners into follow-ups, not merely the index partners; the reason is that many partners separate and some number of new partners are being abused as well, so that contact with the index partners alone is not enough. In some cases, both an index and a new partner are being abused.

For purposes of accountability, programs must provide feedback and information to victims. The nature of a program and information about its effectiveness, along with program evaluation and termination summaries, are important feedback and information elements. In addition, according to a personal communication from D. Adams, documenting violent behavior is vital for use in court proceedings related to divorce, custody, and/or visitation. Finally, controlled effectiveness and other studies of batterer intervention should include information from victims, not just information about perpetrators in official reports, such as police reports, arrest data, and recidivism data.

Domestic Violence Work in Kentucky: A Legislative Perspective

In 1992, Kentucky passed a bill authorizing probable cause arrests for domestic violence for the first time. Previously, police officers were not empowered to arrest someone for a misdemeanor unless the crime was committed in the presence of the officer. The new legislation authorized police officers called in to a probable domestic violence situation to arrest the suspected perpetrator. In addition, Kentucky put into use the Civil Emergency Protective Order (EPO) as a means of addressing domestic violence. This civil order, which can be effective for as many as five years, mandates that the perpetrator of domestic violence engage in no further acts of violence against the victim, have no contact with the victim, and stay completely away from the victim and the victim's family. Mandated arrest of the suspected perpetrator and use of the EPO have proven to be effective tools for quick and direct intervention by the justice system. Violation of an EPO is currently a criminal offense in Kentucky.

Putting these tools to use in Kentucky required laying a lot of groundwork. One major task was training health care professionals, social service groups, agencies, law enforcement groups, prosecutors, and judges regarding these new tools and the dynamics of domestic violence. The training soon paid off in the form of recognition that domestic violence is a special type of crime. For instance, in 1993, Fayette County elected the first woman to serve as the county attorney. She immediately created a domestic violence division of prosecution—a very important step for communities, because when a prosecutor recognizes that domestic violence is a different kind of crime stemming from a very complicated situation, the special needs relating to domestic violence crime can be handled more appropriately.

Those trained to enforce the new law also learned that a characteristic of domestic violence is the reluctance of some victims to prosecute their abusers. The victim of domestic violence is in an intimate relationship in which the victim often loves and does not wish to leave the batterer. In addition, victims may be reluctant to admit the abuse because of embarrassment. After all, it is very embarrassing to tell a mother, a neighbor, a friend, a police officer, or a victim's advocate that the person who is supposed to be loving and cherishing instead metes out physical and verbal abuse. The dynamic of financial dependence may also play a role in a victim's reluctance to prosecute her abuser. Sometimes, the emotional and financial ties of the victim to the abuser are so strong that the victim violates an EPO by seeing the batterer anyway. Prosecuting domestic violence cases is extremely difficult when the

victim either will not testify or violates an EPO and claims that everything is fine.

Successful intervention requires a combination of effective batterer intervention programs and batterer punishment. Kentucky uses both options, because treating batterers is not always possible. Kentucky has established a nine-month batterer treatment plan set up by the Mental Health, Mental Retardation Comprehensive Board. Known as a diversion program, the plan is targeted to younger batterers with little or no criminal history. Those with felony convictions are not considered for the program, nor are older batterers. Typically, an accused young batterer with a relatively minor or no criminal history is offered a plea bargain. Those batterers who accept the plea bargain must attend the diversion program. Upon successful completion of the program, the offender has the charges set aside and dismissed. To ensure that this program works, a multi-disciplinary team made up of the prosecutor, victim's advocates, a sheriff's department representative, a police department representative, a treatment program representative, and sometimes others meets weekly to review and discuss each case.

Unfortunately, the program does not enjoy unalloyed success. In one case, for example, a batterer undermined the program by influencing the other participants in the absence of the counselor by making comments such as, "Why are we here? I work hard. I provide a good living for my wife and my children, and here we are sitting in this group where they are treating us like a bunch of criminals." He was dismissed from the group as a result, and knowing what that dismissal meant to the court, subsequently took his family hostage in what became an eight-hour siege and standoff with the police.

Like many other states, Kentucky has learned that violence in the family is the breeding ground of many ills that our society must pay for in taxpayer dollars—dollars to provide medical treatment for the injuries, to correct the problem, and/or to separate the victims from the perpetrators. Moreover, violence in the family is cyclical. It is known that boys and young men who see their fathers batter are likely to repeat the behavior, and girls in families who see their mothers battered without taking action are more likely to become victims. Battering is culturally reinforced. Accordingly, the messages about the need to stop battering must be taken to the community in which the cultural underpinnings of the practice exist.

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Perspectives on Legal Strategies to Prevent Workplace Violence

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ABSTRACT

Workplace violence is a continuing problem in the United States, accounting for approximately 1,000 deaths each year and for more than 1.5 million incidents of nonfatal injuries. State and federal agencies have published guidelines for preventing workplace assaults, but there is a need for a strong research agenda to address the effectiveness of intervention strategies. After an overview, this article provides a discussion of workplace violence from three perspectives. One section discusses the process used in a manufacturing setting to install a workplace violence prevention program. A second section provides insight into the processes used to fully implement a workplace violence prevention program in a health care setting. A final section provides insight to the processes brought to bear in one state to mandate prevention of workplace violence in the health care setting. There is a critical need to evaluate alternative strategies to address workplace violence, to make the findings available to legislative and executive branches of government, and to implement effective strategies to counter violence in the workplace.

Workplace violence causes a significant number of workplace fatalities and injuries throughout the United States every year. In any given week, approximately twenty workers are murdered and thousands are assaulted while working. Of course, these numbers went up dramatically in 2001, since the vast majority of those killed in the World Trade Center and Pentagon attacks were working at the time. The National Crime Victimization Survey (2001) estimated that 1.7 million violent victimizations per year occurred against persons age 12 or older while they worked or were on duty.

In general, persons unknown to the victims commit most workplace homicides. Moreover, most of the victims work in retail trade, security services, or transit services occupations. These circumstances are in contrast to those that characterize non-fatal workplace assaults. The majority of non-fatal workplace injuries occur in settings in which the victim and the attacker are in a custodial or client-caregiver relationship, such as in health care or social services. According to Bureau of Labor Statistics data for rates of lost-time injuries related to violence and assaults by persons, the public sector is at substantially greater risk than the private sector. This is particularly the case for employees of state government, as demonstrated in Figure 1, which compares the rate of lost-time injuries of workers in United States private firms, private firms in the State of Washington, Washington local governments, and Washington State government.

Figure 1. Comparison of rate of lost-time injuries of workers

	1995	1996	1997	1998	1999
US Private	2.8	2.2	2.5	2	1.8
WA Private	2.5	2.2	2.8	2	1.7
WA State Gov		21.3	31.7	32.6	36.1
WA Local Gov	6.4	6.9	7.7	13.5	10.1

The definition of violence in the workplace includes verbal threats, threatening behavior, or physical assault. The four basic types of workplace violence are:

1. Violence by strangers where the assailant has no legitimate business relationship to the workplace (for example, entering the workplace to commit a robbery);
2. Violence by customers (current or former) or clients (patients, prisoners, students, passengers), usually to those who provide direct service to the public;
3. Violence by current or former co-workers—employees, supervisors, or managers who often seek revenge for perceived unfair treatment; and
4. Violence by an assailant who confronts an individual in the workplace with whom an outside personal relationship exists. Such actions appear to be motivated by perceived difficulties in the relationship or psychological or social factors specific to the assailant.

Workplace violence and assaults are not random; rather, risk factors are associated with such events. For example, common risk factors include

1. Contact with the public;
2. Exchange of money;
3. Delivery of passengers, goods, and services;
4. Having a mobile workplace, as in the case of taxi drivers and police officers;
5. Working with volatile, unstable persons;
6. Working in isolation;
7. Working late at night or in the early morning;
8. Working in high crime areas;
9. Guarding valuables; and
10. Working in community-based settings.

Mental health care workers are at particular risk of assault from patients. Violence directed toward mental health care workers has an extensive and frightening history, including the recent brutal death of Nicole Castro, a Maryland social worker who was conducting a home visit at the time of her murder. According to data collected as part of the Department of Justice National Crime Victimization Survey (NCVS), mental health professionals and custodial workers are at nearly four times the risk of assault relative to all health care workers.[1] In fact, health care workers in all fields are at risk. In 1999, 43% of all non-fatal assaults (n=2,637) resulting in lost work days in all industries in the United States were against workers in the health care industry.[2]

State and federal agencies have responded to these data by publishing guidelines on prevention of workplace assaults. Federal Occupational Safety and Health Administration (OSHA) voluntary guidelines followed a period of several years of federal enforcement activity in workplaces in which violence was a "recognized hazard." From 1993-1995, OSHA issued eight Section 5(a)(1) general duty clause citations for workplace violence. However, OSHA's use of the general duty clause to address workplace violence was curtailed after the agency lost a case at the trial level challenging citations issued in 1995.[3] OSHA did not appeal the administrative law judge's decision.

In 1996, OSHA responded to research findings, union petitions, and growing awareness of the problem of workplace violence by publishing the document "Guidelines for Preventing Workplace Violence for Health Care and Social Service Workers." It should be noted that unions originally petitioned OSHA for a regulatory standard addressing workplace violence and that these union efforts continue. The Federal OSHA guidelines were based largely on guidelines developed in 1993 and incorporated in California's state OSHA plan. The 1996 OSHA guidelines provide an overview and a framework for addressing the problem of workplace violence; the guidelines include the basic elements of any proactive health and safety program: management commitment and employee involvement, worksite analysis, hazard prevention and control, and training and education. These guidelines primarily address Type 1 and Type 2 violence. Examples of recommended control strategies appear in Table 1.

Table 1. Violence Prevention Guidance for Type I and Type II Violence

Type 1 Advice or Requirements	Type 2 Advice or Requirements
Training workers in de-escalation techniques	Training workers (de-escalation techniques)
Posting signs that there is minimal cash in register	Controlling access to worksite
Addressing employee isolation factors	Addressing employee isolation factors
Using a drop safe with limited access	Setting up worksite so workers are not trapped from exiting
Providing outside lighting	Eliminating easy access to potential weapons (e.g., scissors)
Providing a clear, unobstructed view of the cash register	Establishing a client referral/ assistance program
Providing security personnel	Providing security personnel
Establishing a communication method to alert police	Providing a quick communication method to alert security
Increasing police patrols	
Posting laws regarding assault, stalking or other violent acts	Posting laws regarding assault, stalking or other violent acts

The effectiveness of these control measures has been studied only rarely. In those few cases in which rigorous methods have been applied to their study, the measures have been found effective. For example, Loomis et al. found that outside lighting and adequate staffing significantly reduced the risk of fatal assaults due to robberies, as did any combination of five or more administrative controls.[4] Lipscomb is currently studying the effectiveness of a comprehensive violence prevention program in the mental health care setting. A 2000 violence prevention workshop in Washington, D. C. has called for a strong research agenda to address the effectiveness of intervention strategies.[5,6] In the absence of additional research, legislators, administrators, and employers must act in the face of uncertainty. The next two sections provide examples of actions to address the problem of workplace violence, one in the manufacturing and one in the health care setting.

Violence Prevention in the Manufacturing Setting

Violent behavior can occur anywhere, including in manufacturing settings. Although violence may be less common in workplaces closed to the general public and in which most people present in the facility have been subject to some type of pre-employment review of physical and social skills, it is no less traumatic.

This fact was brought home to International Truck & Engine Corporation on February 5, 2001, when an ex-employee who had been fired for theft two years previously and was to surrender to begin serving a prison sentence the following day forced his way into a diesel engine plant and went on a shooting rampage that left four employees and the ex-employee dead. It was a watershed moment for International in the same way that September 11 was for the country as a whole.

Although the scope of violence was a shock, the possibility of violence was not totally unexpected. Ironically, an hour before the shootingbegan, a violence prevention plan had been presented to the executive council of the company in response to recent problem indicators. One such indication was that employee assistance plan (EAP) utilization had increased in recent years. International's EAP provides counseling services for a wide range of problems: financial, family, and psychological. In 2001, 16 % of all beneficiaries (employees and families) made use of the services, about double the historical average. Another indicator was mental health drug costs paid under the company's prescription drug plan, which accounted for 8 % of total pharmacy costs; most of the usage was prescribed outside a treatment program. In the prior three months, an unusual number of threats or physical violence had required disciplinary action. If there were any doubts about the need for a program to address workplace violence, events later in the day erased them, and International soon had a violence prevention program in place.

International's violence prevention program aims to prevent hostile and violent, not merely illegal, behavior. The program's several elements include written policies and procedures, hiring practices that screen for violence proneness, mental health self-assessment tools, crisis management/threat assessment teams, training in

awareness and prevention, and a plan for post-incident management and services.

Health and productivity are powerful motivators in a manufacturing setting. The precursors of violence create a climate that is both destructive and counterproductive. Most companies strive to promote a positive, high-performance culture. Increasingly, the characteristics of violence-prone behavior are being recognized as incompatible with establishing that kind of work environment. Thus, a violence prevention program is not merely a tool to prevent tragedy, but a vital part of a strategy to improve health and productivity.

Violence Prevention in the Health Care Setting

The OSHA guidelines discussed previously provide an outline for developing a violence prevention program, but because they are performance-based, it is up to stakeholders within the industry to do the painstaking work of implementing them in a manner that will yield results. The New York State Office of Mental Health (OMH) and the Multi-Union Health and Safety Committee (MUHSC) are the first to evaluate the effectiveness of these guidelines in the institutional mental health setting.

In 1999, the National Institute for Occupational Safety and Health funded a collaborative effort between the University of Maryland School of Nursing and the MUHSC to evaluate the guidelines. The primary goal of the project is to reduce violence against health care workers in state mental health institutions. To achieve that goal, the project will document and describe a process for implementing OSHA violence prevention guidelines within in-patient mental health facilities and compare assault rates, risk factors for assault, and job satisfaction in these facilities one year prior to and one year following implementation of a comprehensive OSHA guideline-based violence prevention program.

Several factors have made this kind of study possible. The unions representing OMH workers have strong health and safety contract language that supports such efforts; the MUHSC provides a forum to develop violence prevention initiatives. Pilot projects had been conducted at two OMH facilities in 1996, and in 1998 OMH issued a Safe and Therapeutic Environment Program policy requiring each mental health facility to develop a violence prevention program according to OSHA guidelines. The existence of these conditions made OMH an ideal setting in which to conduct and evaluate this natural experiment.

Early in the project, a statewide advisory group was formed and a Request For Application was sent to all 28 facilities. The criteria for site selection included the existence of management commitment of resources to develop and implement a program, the presence of an active health and safety committee, and the availability of computerized assault data. Of seven applications received, OMH selected four facilities as intervention facilities. Later, three mental health facilities were selected to serve as controls. Joint labor-management advisory groups at the facility level took responsibility for implementing a facility-specific program at each intervention site.

A primary activity of these advisory groups was to conduct a comprehensive risk assessment of the wards to be studied, with strong input from direct care providers and from an architect who specializes in design of secure state buildings. This assessment, which included a baseline staff survey, provided direction to develop the specific intervention activities.

The intervention consists of a number of distinct, ongoing hazard control activities. One activity was administration and study of results of an environmental survey, which identified a multitude of short- and long-term recommendations that were presented to the local advisory groups for discussion and action. A one-day“solutions-mapping” training session was conducted within the four facilities in May/June 2002. Focus group, environmental, and staff survey data were presented to direct care staff during these sessions. These data were then used in the solutions mapping exercise.

Results of the study to date include the implementation of most short-term environmental recommendations and an action plan for addressing the long-term items. Focus group discussions led to the identification of the following strategies for preventing workplace violence and its consequences:

1. Ensuring equal commitment to worker safety and health and patient/client safety, along with zero-tolerance for threats and physical assaults and communication of this message to managers, supervisors, staff, patients and visitors.
2. Maintaining alarm systems and other security devices and arranging for a reliable response system when an alarm is triggered.
3. Implementing a comprehensive program of medical and psychological counseling and debriefing for staff experiencing or witnessing violence, together with support for staff choosing to file charges against alleged perpetrators.
4. Ensuring adequate and qualified staff coverage at all times, in particular during patient transfers, emergency responses, meal times, and at night.

The staff survey was pilot tested, revised, and completed by nearly 500 OMH direct care staff (90% response rate) in spring/summer 2001. A post intervention survey will be administered in the spring/summer of 2003. A comparison of pre- and post-intervention survey data will follow.

Legislative Action on Workplace Violence

Often, legislators find themselves needing to act before research on a problem is complete. The legislative process has been used to bring various stakeholders together to develop a viable plan for tackling social problems through regulation. Several states, including California, Florida, and Washington, have used the legislative process to address workplace violence prevention, primarily in late night retail and health care settings. A catalyst is often a dramatic event, such as a workplace homicide, or a series of events that are brought to the public's and therefore legislators' attention via the media. Once concerned citizens contact their legislators, legislative staff members must conduct research and check with various agencies and researchers for information, determine what other states have done on the issue, and bring together concerned stakeholders to craft legislation to address the issue. A series of negotiations take place within the legislative chambers, in the governor's office and with stakeholders to develop an acceptable bill that begins to address controversial issues.

Washington State provides one example of state political action to address workplace violence. In 1990, legislation directed the Department of Labor and Industries to develop and implement regulations to prevent workplace violence in late night retail facilities; in 1999, legislation addressed the problem in health care settings, and in 2000 an act extended provisions to psychiatric hospitals. A brief history of the process involved in passing legislation to address workplace violence in health settings can be instructive for other states considering similar legislation.

Assaults at the state psychiatric hospitals had been reported in the press in the early 1990s. The Service Employees International Union (SEIU) and the American Federation of State, County and Municipal Employees (AFSCME), representing workers at these and other hospitals, demanded action by the legislature. The legislature requested that the Department of Labor & Industries conduct a study of the problem. That department's research group, Safety and Health Assessments and Research for Prevention (SHARP), analyzed workers compensation claims, interviewed management and workers at the hospitals, and conducted a survey of employees. The survey identified more than four physical assaults per caregiver per year. The incidence of assault-related workers compensation claims was 14 per 100 worker-years.[7] SHARP developed a number of recommendations to address workplace violence problems, including (a) providing for adequate facility staffing to

ensure that all staff attend de-escalation, restraint, and containment training, and (b) staffing for acuity and installing personal alarm systems. Another recommendation was to provide structured psychological support for assaulted employees. Additionally, in 1997, a Department of Labor and Industries technical report on workers compensation claims rates for work-related assaults called attention to the high rates in health care, particularly in psychiatric hospitals.[8]

Senate bill 5312, an act relating to prevention of workplace violence in health care settings, was introduced in the 1999 legislative session. The bill required health care employers, including state and private hospitals, mental health evaluation and treatment facilities, home care agencies, and community mental health programs, to develop and implement workplace violence protection programs. SEIU and AFSCME were the main proponents of the bill. The Department of Social and Health Services (DSHS) successfully excluded state hospitals from the legislation by having a null and void clause added. Later in 1999, several highly publicized assaults resulting in injuries occurred in the state psychiatric hospitals. In the 2000 session, House bill 2899 was introduced to develop a workplace safety plan for state hospitals. This time, DSHS requested coverage by the legislation, and the bill passed both chambers. Together, the enacted bills called for employers to conduct assessments to identify potential security and safety hazards. Employers were to identify actual and potential violent actions and to determine and implement appropriate preventive action to address hazards, including making appropriate changes in the physical environment, staffing, training, personnel policies, first aid, and reporting procedures.

Health care settings (excluding nursing homes, but including state mental hospitals) were required to have their plans in place and to begin keeping records and training employees by July 1, 2000. To date, the Department of Labor & Industries has not begun any enforcement initiative. However, the department, responding to complaints, has issued several citations. The effectiveness of a regulation without an enforcement initiative remains to be determined. Workers compensation claims rates for assaults will continue to be monitored and reported to the Department, to the legislature, and to the affected communities.

Conclusion

Workplace violence is a threat to virtually all workplaces. It is not random; risk factors have been identified across work settings. There have been a number of regulatory and legislative actions to address workplace violence where it is most prevalent (e.g., late night retail, health and social services). The efficacy of different strategies to prevent workplace violence has not been adequately studied, and a critical need exists to evaluate strategies and to make findings available to legislative and executive branches of government, as well as to business and labor organizations, so that effective strategies can be widely implemented.

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On the Edge of Tomorrow: Fitting Genomics into Public Health Policy

Susan Gerard, Maxine Hayes, Mark A. Rothstein

ABSTRACT

The project to map the human genome and the field of genetics in general offer unique opportunities for not only clinical medicine, but also for public health to address and prevent disease. At the same time, genomics is fraught with ethical challenges, not the least of which is how to prevent misuse and abuse of genetic information by virtue of the legal powers conferred on public health organizations. This article examines the role that public health can perform in the 21st Century in using the knowledge gained from the human genome project, including how to address the barriers to widespread application. The article also examines the challenges facing public health in dealing with the legal and ethical issues arising from genomics and in avoiding misapplication. While the opportunities that genomics offers public health agencies are unprecedented, so too are the challenges, which include the fact that genomics exists within a legal and policy paradigm that is the opposite of the one in which public health has traditionally existed. The danger of abuse and misuse, therefore, is very real.

The Human Genome Project and other recent genetic/technological advances present unique opportunities not only for clinical medicine, but for public health as well. Research in the next decade will bring an understanding of disease and associated gene variants, as well as an understanding of the influence of the environment and behavior on genetic variation. We will continue to see the proliferation of tests to identify individuals with genetic disorders as well as asymptomatic individuals with genetic predispositions to particular disorders. As we try to fit genomics into public health policy, public health leaders and elected policymakers are eager to find the right framework—legal and policy—for the decisions to be made in public health policy and practice.

Because of the efforts of many federal partners, the eyes of the public health community are wide open. Public health officials are beginning to understand the implications of the Human Genome Project for public health. However, significant challenges confront the public health community, especially in the translation, interpretation, and actual application of all this "new" knowledge. Discussion of these issues has occurred in a variety of venues over the past 5–7 years. In particular, the focus has been on the proper framework to be used for making decisions about how to process and apply the knowledge gained.

Historically, public health has been involved in genetic services only as they relate to maternal and child health. We can, however, learn from our successes in large, population-based services such as newborn screening programs. For example, in the more than 40 years of genetic newborn screening in Washington State, there have not been any breaches in confidentiality or privacy, contrary to widespread fears that genetic

testing might open the doors to unauthorized proliferation of genetic information. The absence of breaches of confidentiality and privacy is attributable to the fact that Washington State enforces policies regarding handling, access, and storage of DNA material.

However, moving beyond genetic services for maternal and child health and for the health of children with special health needs to genomic applications of new knowledge to adults of all ages is a new place for public health. Finding optimal ways to integrate all the knowledge into disease prevention and health promotion is our current task. Disease management strategies that consider early identifiable risks will help us tailor our health promotion and disease prevention messages for segments of the population in ways we have never been able to before.

Genomics will be to the 21st Century what infectious disease was to the 20th Century for public health. It has the potential to change our thinking. Genomics should be considered in every facet of public health: infectious disease, chronic disease, occupational health, and environmental health, in addition to maternal and child health.

What are the barriers to getting to this new place? First, there is a necessity to have a competent workforce with a new mindset. To aid in this effort, the Association of State and Territorial Health Officials already has a genetics task force that is working on a toolkit to help public health leaders and policy makers with some of the decisions they will have to make. The Maternal Child Health Bureau has encouraged state health agencies to develop state genetics plans and to work with broad-based advisory committees on confidentiality and privacy issues, to examine current state laws protecting access to genetics information, and to protect people from discriminatory practices in insurance coverage. The Centers for Disease Control and Prevention (CDC) has urged chronic disease program directors to apply genomics much as they currently apply epidemiology to all facets of their program planning. The other barrier to application of genomics in public health is the "silo" mentality within programs in public health organizations. Public health management needs to break the categorical silos down within programs and ensure that these programs work together. Looking at genomic information in the way we look at epidemiology is one way to change the silo mentality so common among public health programs.

Lastly, state and local health agencies today are very compromised with their dwindling funding bases from which to operate. They are going to need a lot of help to successfully use the new knowledge that genomics brings and to provide assurances that people are helped, not harmed, in the process. The whole objective must be to focus on improving health status. The support of the genetics centers funded by CDC will hopefully produce additional tools and supports for states in their work with clinical medicine, particularly in primary care.

The core functions of public health—assessment of information on the health of the community, comprehensive public health policy development, and assurance that public health services are provided to the community—and the ten essential public health services listed in *Healthy People 2010* form the policy framework for public health's role in Washington State. This policy framework can serve as a model for the application of genomics in public health in general. Examples of the roles that public health can perform are assessment of the need for access to genetics services, assurance of the availability of appropriate testing and counseling, evaluation of quality of services, data collection and data security, and assurance of confidentiality and privacy.

This policy framework relies upon a strong science base while keeping the focus on improving health status. The core function policy framework is one that could work across all levels of government. At the same time, it is necessary to have new partnerships if public health is to be successful in the application of genetics even within this framework. A key new partner will need to be primary care providers.

Public Health and Genetics: A Cautionary View

The greatest challenge facing public health genetics is defining the scope of the enterprise. It is tempting for public health officials to reason that because newborn screening programs have been successful, a similar model should be used for broader population-based interventions. The basis for such reasoning is that if genetic testing is valuable for one person, then it must be really valuable on a population-wide basis, and the government should therefore become involved in financing, administering, and perhaps even requiring participation in the program.

Almost by definition, however, public health and genetics are incompatible. Public health is based on utilitarianism and paternalism. The benefit to society as a whole justifies coercive measures that outweigh individual rights. Consequently, a whole range of interventions—from immunization to isolation—may be justified. Genetics, on the other hand, has a completely different philosophical grounding. The intensely personal, inter-generational, and reproductive aspects of genetics have given rise to a professional ethos of non-directive counseling, autonomous decision-making, and individual rights—the very opposite of the approach of public health.

The concerns are more than theoretical and conceptual. Historically, when public health and genetics have been linked, the results have invariably been disastrous. For example, public health was the justification for involuntary sterilization laws (and this year we mark the 75th anniversary of the Buck v. Bell decision). In addition, maintaining the public health has been used to justify laws barring immigration from parts of the world whose population was deemed inferior to the dominant Northern European population and for laws prohibiting inter-racial marriage and inter-racial blood transfusions. Public health was also the justification for the ill-conceived, compulsory sickle cell testing programs in the late 1960s and early 1970s. And, of course, beyond genetics, public health has been used to justify numerous unethical research activities ranging from the Tuskegee syphilis study to the radiation experiments and the research involving prisoners, children, and mentally incompetent patients. This all-too-recent history demands that any actions in the field of public health genetics proceed cautiously, with clearly articulated goals and methods and with public involvement and accountability.

Very little recent genetics legislation at the state and federal levels addresses public health issues. At the state level, we have seen a significant expansion in the number of newborn screening tests performed. The other main legislative effort at the state level is the enactment of genetic privacy and nondiscrimination legislation. At least 43 states have enacted laws prohibiting genetic discrimination in health insurance, and at least 30 state laws prohibit genetic discrimination in employment. Other states have enacted laws protecting genetic privacy by requiring informed consent for any genetic testing. Although genetic nondiscrimination legislation has languished in Congress for years, the Health Insurance Portability and Accountability Act (HIPAA) prohibits discrimination based on genetics in group health plans.

The connection of these types of laws to public health is that if individuals believe that their genetic test results can be obtained and used by third parties such as employers and insurers, they will be reluctant to undergo genetic testing, including testing that may have considerable value in disease prevention. An example is testing for predisposition to colon cancer, with results possibly indicating to insurers the need for more frequent colonoscopies. It is not clear whether these laws barring discrimination in health plans have had any effect, in part because the laws provide inadequate protection and in part because genetic testing has not yet become a standard part of primary care and care in most specialty areas of medicine.

It is therefore extraordinarily important to define what we mean by *public health*. There has been a regrettable tendency to call any activity that

attempts to improve the health of two or more people "public health." But as public health lawyers know, public health is a field defined by law. Public health officials derive their authority and their mandate from constitutions, statutes, and regulations. The involvement of public health officials and the invocation of coercive powers must be limited to threats to the public's health (such as in the case of infectious diseases). The public threat is what justifies the incursions on individual rights. Public health, then, is not the same as population health, which might be defined as measures to promote the health of the population through education, health promotion, and treatment on a voluntary basis by private as well as public actors. Public health also is not a substitute for individual health services provided in clinical settings. In short, we need to carefully define and delineate the responsibilities of the various individuals and entities in public health genetics.

C.S. Lewis has said, "Man's power over nature turns out to be a power exercised by some men over other men with nature as its instrument." We must be vigilant to ensure that our newfound power over genetics is not exercised on our weakest and most vulnerable citizens under the heading of "public health."

Conclusion

The new frontier opened by genomics offers public health an opportunity to apply new knowledge in the effort to prevent and treat diseases that currently threaten the public's health. However, it is essential that public health agencies develop an appropriate policy and legal framework for applying the new knowledge. A framework based on the core functions of public health—one that also breaks down the traditional categorical silos in public health programs—is a necessary prerequisite to effective widespread application of genomics in the public health arena. At the same time, it is important to recognize that genomics and the entire field of genetics is potentially dangerous ground and that public health is not the same as population health. The legal powers conferred on public health agencies currently permit those agencies to perform their functions to protect the public's health, but those same powers applied within the new frontier can foster abuse and misapplication of genetic information. Public health professionals will need to tread very carefully as they develop a framework for including genomics in their arsenal of weapons to perform public health's core functions.

Will Biomonitoring Change How We Regulate Toxic Chemicals?

Richard Jackson, Paul Locke, Jim Pirkle, F. E. "Ed" Thompson, Dorothy Sussman

ABSTRACT

Biomonitoring is the assessment of human exposure to environmental chemicals by measuring the chemicals or their metabolites in human specimens such as blood, urine, saliva, or tissue. It has become a powerful public health tool. This article discusses the practical application of biomonitoring to address a public health problem in a state, to explain how biomonitoring differs from predicting exposure through environmental monitoring, to describe the influence biomonitoring has had on promulgating regulations aimed at protecting public health, and to discuss the position biomonitoring holds in the legal landscape as well as its promise in forging laws that will regulate toxic chemicals more effectively.

In March 2001, the Centers for Disease Control and Prevention (CDC) released its *National Report on Human Exposure to Environmental Chemicals*, a major scientific assessment detailing the U.S. population's exposure to 27 environmental chemicals—24 of which were assessed for the very first time.[1] Scientists at CDC's National Center for Environmental Health Laboratory used a technique called biomonitoring to assess exposure among people participating in CDC's ongoing National Health and Nutrition Examination Survey, or NHANES.

Biomonitoring has become a powerful public health tool. CDC has been measuring environmental chemicals in people for more than 25 years, both for national studies of population exposures, such as NHANES, and for studies that examine exposures to specific populations. For the first *Report*, however, Americans got a glimpse of 27 chemicals that they are exposed to in the environment—from the ubiquitous metal, lead, to certain everyday pesticides and a host of plasticizers called phthalates. The next *Report*, which will be published in late 2002, will contain biomonitoring data on at least 75 environmental chemicals, including the 27 that appeared in the first *Report*.

This article discusses the utility of biomonitoring from three vantage points. First, it discusses an event illustrating the value of biomonitoring in one state, Mississippi, as a typical way of addressing serious public health problems within a state's borders. Next, it provides a primer on biomonitoring. Finally, the article contains a discussion of the positioning of biomonitoring in the legal landscape and the promise it shows in helping to regulate toxic chemicals more effectively.

Biomonitoring in Mississippi

In November 1996, just before Thanksgiving, health officials in southern Mississippi identified several homes whose interiors had been sprayed with the pesticide methyl parathion. This chemical was sprayed by two unlicensed pesticide applicators operating independently of each other to rid homes of cockroaches. Methyl parathion has been used outdoors, but it is not licensed for indoor use.

This was not the first time that Mississippi health officials had seen the effects of indoor spraying of methyl parathion. In 1986, in Tunica, Mississippi, the pesticide was used at three times its field strength to kill spiders in a home. As a result, two children died, and three other people were hospitalized. With that incident clearly in mind, health officials were greatly concerned about human exposure to this latest illegal spraying, and that concern only heightened when the officials soon discovered that not merely a few homes, but rather 2,700, had been sprayed with the pesticide.

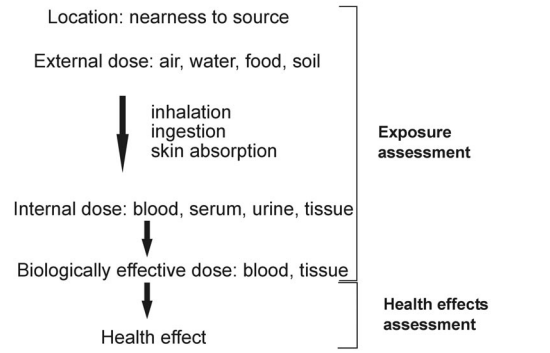
Multiple factors made the situation in southern Mississippi even worse. Remediation of contaminated homes was the only known way to render those homes safe for habitation, and the estimated costs associated with this work were approximately $50,000 per home. While such work was being done, families would have to be relocated at public expense. At the time, Mississippi's casino building boom was at its height, with its demand for housing for workers; no housing was available for the 400-plus families and businesses that would have to be relocated. Instead, these families and businesses would have to be housed in motels for extended periods, because remediation efforts were behind schedule.

The Mississippi State Department of Health requested assistance from CDC's National Center for Environmental Health Laboratory to conduct biomonitoring by measuring levels of a metabolite of methyl parathion in people's urine. As a result of having reliable data about which people were actually exposed to the pesticide and the level of exposure, health officials were able to make several key public health and policy decisions. For instance, officials established which houses needed remediation and which did not. That ability to reach a determination resulted not only in savings of hundreds of thousands of dollars in remediation and relocation costs, but also in lessening health concerns among homeowners. Knowing urinary levels of the metabolite also helped health officials determine which families needed to move immediately and which could continue to live in their homes.

Other Uses for Biomonitoring

The distinguishing feature of biomonitoring is that it assesses exposure to chemicals by measuring levels of the chemicals or their metabolites in human blood, urine, saliva, or tissue rather than in air, water, soil or dust, or food. CDC scientists have developed new analytic methods and improved existing ones, making them faster, more accurate, easier to perform, and less costly. Currently, CDC's Environmental Health Laboratory can measure more than 250 chemicals in people's blood, urine, saliva, or tissue. However, the mere fact that people have an environmental chemical in their bodies does not mean that the chemical causes disease. Rather, it is necessary to establish a connection between the chemical and the disease. An exposure and health-effects pathway shows that there are multiple steps between exposure and disease.

Figure 1. Exposure and Health Effects Pathway



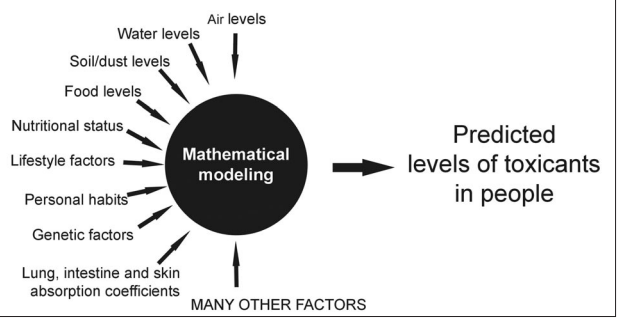
Assessing exposure involves determining how near people are to the source of that exposure; measuring levels of that chemical in air, water, soil or dust, and food (a process known as environmental monitoring); and measuring the internal dose in blood or urine (commonly referred to as biomonitoring). Ideally, measuring the concentration of the chemical at the toxic site (biologically effective dose) provides the most health-related dose measure, but organ biopsies are almost never practical in health studies.

Predicting levels of toxicants in people by use of traditional environmental monitoring is difficult, involving many considerations, including making

assumptions about people's personal habits (such as hand-to-mouth activity), lifestyles, genetic factors, absorption coefficients, and estimates of the levels of toxicants in multiple environmental media.

This information is then put into mathematical models that predict blood and urine levels.

Figure 2. Predicting Levels of Toxicants in People Using Environmental Monitoring is Difficult and Includes Many Assumptions



However predicted, blood and urine levels of toxicants frequently are markedly different from measured levels. In contrast, biomonitoring measures (rather than predicts) the toxicants that actually get into people and the concentrations of those toxicants. The value of biomonitoring lies in decreasing the uncertainty associated with assessing human risk and vastly improving the ability to make timely and appropriate public health decisions and regulations. As a result, scarce resources can be used to address serious problems rather than those that are of negligible health concern.

Figure 3. Human Studies Using Blood Lead as the Measure of Exposure Have Found Health Effects at Lower and Lower Blood Lead Levels

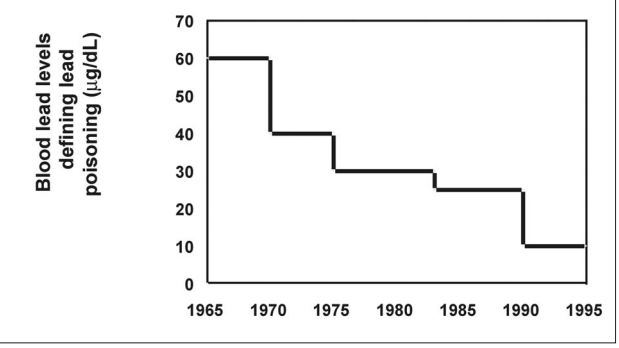
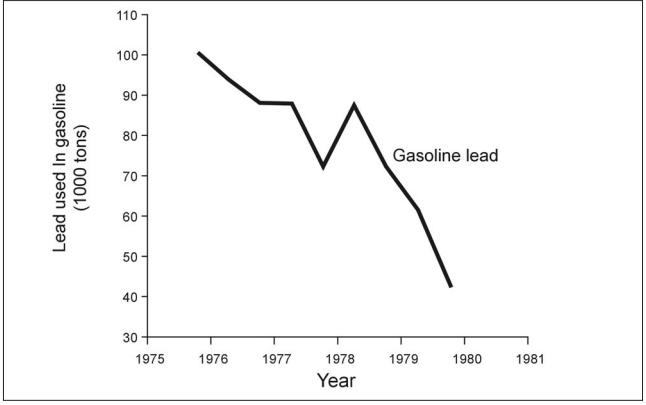


Figure 3 shows how CDC used biomonitoring data to determine the toxicity levels of lead. In the 1960s, lead poisoning was defined as a blood lead level of 60 micrograms per deciliter (g/dL) or greater. By 1990, advances in biomonitoring allowed CDC to measure significantly lower blood lead levels and to correlate those levels with adverse health effects, resulting in the agency's lowering the blood lead level of concern to 10 g/dL. Current research is examining whether levels as low as 5 g/dL can cause health effects. Clearly, the toxicity of lead has not changed, but the ability to track lead exposure by use of biomonitoring and to use biomonitoring measurements in health studies has advanced tremendously. As a consequence, CDC has substantially improved its understanding of health risks associated with different levels of lead exposure.

The removal of lead from gasoline is a good example of how biomonitoring information influences the regulatory process. From 1976 through 1980, overall use of lead in gasoline declined as a result of the introduction of unleaded gasoline (Figure 4).

Figure 4. Lead Used in Gasoline Declined from 1976 through 1980



Unleaded gasoline was introduced because lead interfered with the operation of catalytic converters in automobiles. In 1981, the U.S. Environmental Protection Agency (EPA) was considering regulatory changes that would allow increasing the amount of lead in leaded gasoline because lead was an inexpensive octane booster. Environmental monitoring data and modeling predicted that leaded gasoline had little effect on blood lead levels in people (Figure 5).

Figure 5. Environmental Modeling Predicted only a Slight Decline in Blood Lead Levels in People

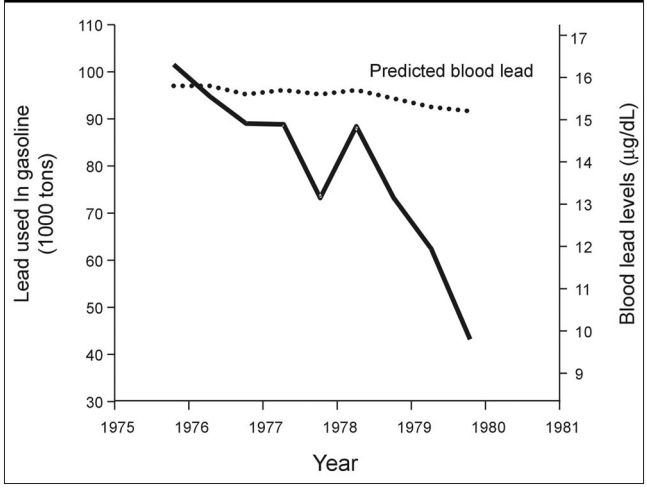
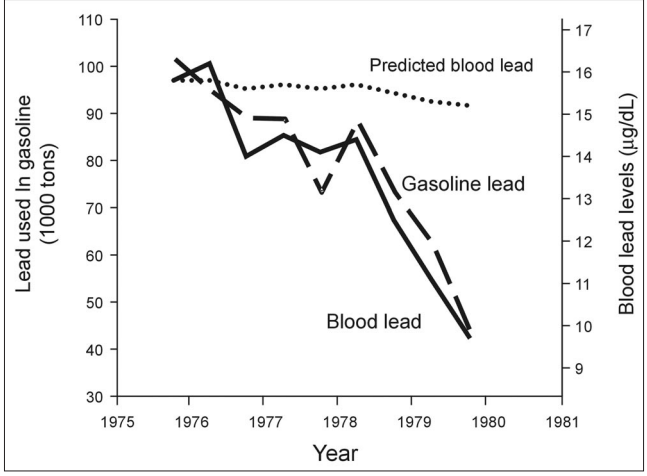


Figure 6. Lead in gasoline and lead in blood NHANES II, 1976-1980

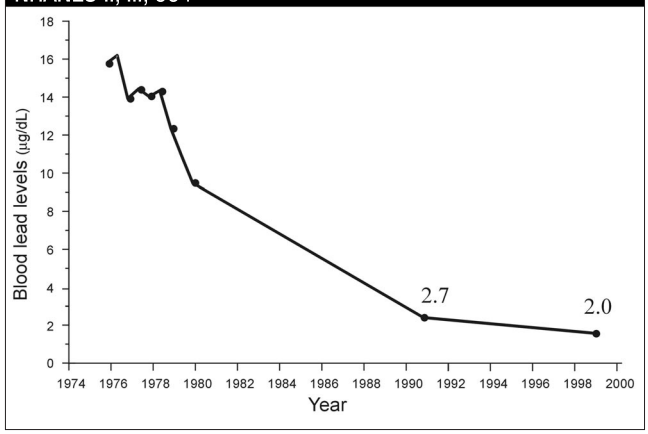


However, results of CDC's second national survey (NHANES II), covering the years 1976 through 1980, showed that declines in actual blood lead levels measured in people matched declines in levels of lead in gasoline (Figure 6).

This critical finding was a major consideration in EPA's decision to reverse its policy and to further restrict the use of leaded gasoline. As remaining lead was removed from gasoline, lead levels measured in humans continued to decline. By 1999, geometric mean blood lead levels had fallen to 2.0 g/dL (Figure 7).

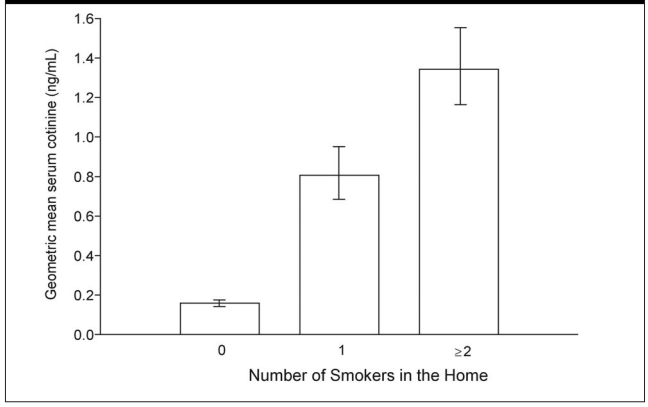
Similarly, people's exposure to environmental tobacco smoke (ETS), which has been identified as a human carcinogen, is another important public health concern. Cotinine is a metabolite of

Figure 7. Blood lead levels in the U.S. population 1976-1999 NHANES II, III, 99+



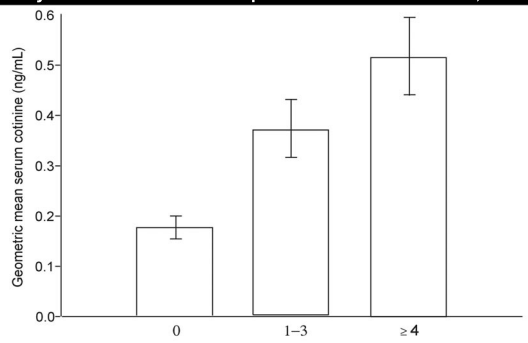
nicotine that tracks exposure to ETS among nonsmokers. Higher cotinine levels reflect more exposure to tobacco smoke than do lower levels. When CDC developed a method for measuring low levels of cotinine in the U.S. population, it found that 88% of the nonsmoking population was exposed to tobacco smoke.[2] Extremely limited information was available on ETS exposure of workers who were nonsmokers but who were potentially exposed in their work environments. CDC's study of nonsmokers showed that cotinine levels (i.e., tobacco smoke exposure) increased with the number of smokers in the home and also increased with the number of hours that workers reported being exposed to tobacco smoke in the workplace.

Figure 8. Serum Cotinine Levels (Geometric Mean and 95% Confidence Interval for Non-tobacco Users in the U.S. Population Ages 4 Years and Older by Number of Smokers in the Home: NHANES III,1988-1991)



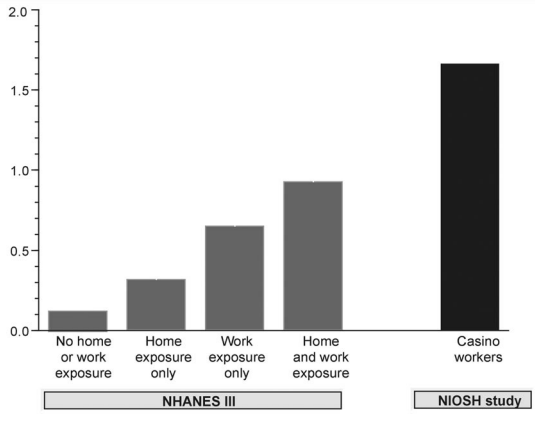
These unique data provided important documentation of worker exposure to ETS and were thus influential in addressing indoor air regulation of smoking in the workplace.

Figure 9. Serum Cotinine Levels (Geometric Mean and 95% Confidence Interval for Non-tobacco Users in the U.S. Population Ages 17 Years and Older by Number of Smokers Exposed at Work: NHANES III,1988-1991)



CDC also has used biomonitoring data from a series of studies to determine how levels of a chemical found in people in one study compare with levels found in many other studies. For example, CDC's National Institute of Occupational Safety and Health (NIOSH) conducted a study of ETS exposure among casino workers to compare their cotinine levels with levels found in the U.S. population during NHANES III (1991-1994).

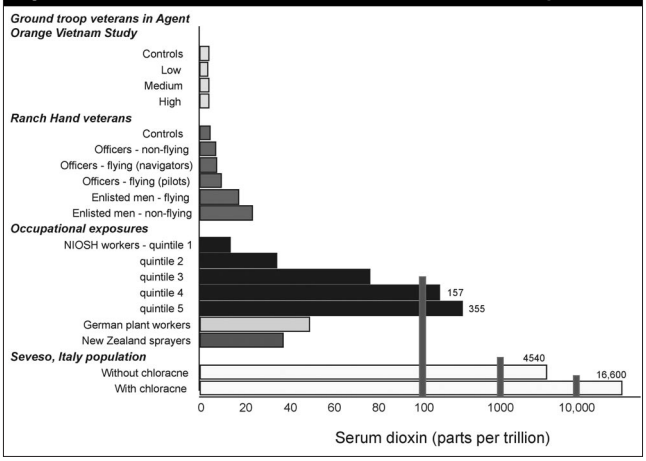
Figure 10. Exposure of Casino Workers to Environmental Tobacco Smoke



The higher cotinine levels of casino workers guided NIOSH actions that limited subsequent worker exposure. These examples illustrate how biomonitoring can be used to reinforce regulatory actions by providing actual data about which chemicals get into people and at what levels. When cotinine levels in the United States population were measured again in 1999, CDC found that there had been at least a 75% decrease in median cotinine levels among people aged 3 years and older. This dramatic reduction documents an important public health success; however, ETS exposure remains a major public health concern.

We can also compare levels of dioxin that were measured in various groups of people for many different studies. Median serum dioxin levels among people exposed to dioxin during the spraying of Agent Orange in Vietnam can be compared to levels in people who were occupationally exposed or who were exposed as a result of an industrial accident, such as the one that occurred in Seveso, Italy, in 1976. Such comparisons provide critical information for deciding what actions may be necessary and useful for protecting the public's health.

Figure 11. Median Serum Dioxin Levels in Selected Populations



CDC's Environmental Health Laboratory is a CLIA-certified medical laboratory. It provides high quality; state-of-the-art biomonitoring exposure data that help policy makers make informed public health and regulatory decisions currently and for the foreseeable future. CDC is sharing that knowledge with states through a biomonitoring grant program that is training state public health laboratories to use analytic methods that measure people's exposure to a wide range of environmental chemicals. Currently, 33 states participate in the grant program, which is aimed at increasing the states' ability to conduct biomonitoring to address environmental health problems within their jurisdictions.

Biomonitoring in the Legal Landscape

An examination of federal environmental laws reveals no single "organic" environmental protection statute; instead, about 25 specific, topic-based or media-based statutes currently exist. A handful of these statutes, frequently referred to as the "Big Seven," are most often associated with public health: the Clean Air Act; the Federal Water Pollution Control Act, more commonly known as the Clean Water Act; the Toxic Substances Control Act; the Federal Insecticide, Fungicide, and Rodenticide Act; the National Environmental Policy Act; the Resource Conservation and Recovery Act; and the Comprehensive Environmental Response, Compensation, and Liability Act, which created the Superfund Program.[3] Although the major goal of each of these powerful statutes is the protection of public health and welfare, their focus is on meeting ambient standards, cleaning up pollution, providing information, and reducing risk to human health.[4] Because using biomarkers to assess exposure is required neither by law nor by regulation, their use is often an afterthought. However, biomarkers have been used successfully to aid regulatory decision making, and many additional potential uses for biomarkers exist. Among these are (a) improving risk assessment (especially its exposure assessment step);[5] (b) establishing baselines or reference ranges; (c) facilitating people's right to know what chemicals are in their bodies; (d) establishing priorities for tackling environmental health-related problems; (e) identifying health disparities (e.g., although blood lead levels have continued to decline among most children, poor children living in housing built before 1960 are more likely to have elevated blood lead levels than children who live in newer homes and are more likely to have elevated cotinine levels because they are exposed to higher levels of ETS); and (f) evaluating interventions to determine their effectiveness.

The challenges associated with biomonitoring are formidable. The need for coordination among federal agencies is important because each agency has separate responsibilities and each is working to solve a separate piece of the environmental health puzzle.[6] It is hoped that the work of the Trust for America's Health to improve the nation's public health infrastructure by establishing environmental health tracking will also improve coordination among various agencies. Another challenge stems from the fact that environmental laws and regulations governing toxic chemicals are highly complex. A further challenge is to incorporate biomonitoring data with environmental modeling. Because many environmental protection programs are precautionary in nature, decision-making is frequently based on models that forecast potential risk. Biomonitoring can greatly improve the assessment of human risk and thus help decision makers determine an appropriate course of action.

Conclusion

Biomonitoring potentially can help the public health and legal communities regulate toxic chemicals more effectively. For example, EPA is beginning to regulate organophosphate pesticides as a group rather than licensing each one separately, so that knowing whether levels of these pesticides in the population are increasing or decreasing will become extremely important. In addition, biomarkers pertaining to dioxin exposures could help answer many questions about exposure. Improving our knowledge about actual levels of chemicals in people improves our understanding of true health risks and ultimately helps us develop sound public health policies and regulations to address those risks.[7]

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Preparedness On The Frontline: What's Law Got To Do With It?

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ABSTRACT

The article provides an overview of current work toward identifying core competencies for public health emergency and bio-terrorism response, including law-related competencies. It demonstrates how competency sets are interrelated and how they provide a framework for developing preparedness training for public health leaders, public health and health care professionals, law enforcement, public health attorneys, and others. The health and safety of America's communities hinge on the nation's public health workforce—the estimated 448,254 public health professionals and 3 million related workforce professionals who form the expanded public health system that protects us during times of national crisis and in our daily lives. The response capacity of our health agencies and communities and their ability to respond effectively will be unpredictable without adequate training. Education in the core competencies in emergency preparedness and bio-terrorism response is essential. Preparedness at the front-line means that public health leaders and administrators must be able to communicate information, roles, capacities, and legal authorities to all emergency response partners during planning, drills, and actual emergencies. Each public health worker must be able to describe his or her communication role in emergency response within the agency, with the media, and with the general public. Law enforcement and state government representatives must understand the legal powers of their agencies and of public health agencies for coordinated response, mitigation, and recovery efforts in a public health emergency event.

Six strategic elements are required for effective long-term improvements in workforce preparedness for health emergency and bio-terrorism response:[1]

1. Monitoring the workforce composition;
2. Identifying competencies and developing curriculum;
3. Designing an integrated learning delivery system;
4. Using incentives to assure competency;
5. Conducting evaluation and research; and
6. Ensuring financial support.

The number of public health workers is estimated at 448,254.[2] This represents a decrease in the past twenty years in the ratio of public health workers to population served. We have little information about the job functions and credentials of this workforce. National efforts are underway to identify core competencies required by individuals for 21st century public health practice. The identification of required competencies and the development of a related curriculum provide guidance for training, retraining, and preparedness of the workforce. Public health law competencies are an important part of the knowledge base needed for practice and especially for preparedness for bioterrorism.

This article provides an update on bioterrorism preparedness competencies, reflections from public health leaders on the new challenges associated with bioterrorism, and insights from law enforcement based on experiences during the anthrax outbreaks in Fall 2001.

Public Health Competencies for Bioterrorism Response

The public health infrastructure includes systems and relationships, data and information, and a prepared workforce. The public health systems themselves include public health law and the public health regulations and powers. The public health relationships include the related partners, such as legal and law enforcement partners. Information needed for a response to bioterrorism includes epidemiologic information, legal data, and forensic data. Having a workforce prepared for a bioterrorism response means that the workforce is competent to use the information and to work within the relationships. While the various public health infrastructure components are often presented as equal, the workforce's competency may be the most important infrastructure element.

The public health competencies necessary for an effective and efficient response to bioterrorism include a complex combination of knowledge, skills, and abilities demonstrated by organization members.[1] Those competencies are also defined as a combination of observable and measurable skills, knowledge, performance behavior, and personal attributes that contribute to enhanced employee performance and organizational success.[3] In short, competencies go beyond knowledge or attitudes; they also describe how the workforce behaves.

Because these competencies reflect work performance in relation to emergency preparedness, it is useful to draft competency statements and to ensure that guidelines and activities within the work environment emphasize emergency preparedness. Among the activities associated with such work environment tasks are:

1. Updating and revising job descriptions. Each job description should include a reference to emergency responsibilities and tasks. It should be clear whether or how there is an obligation to be part of emergency response.
2. Orienting and training employees. The competencies should be meaningful in the context of the agency's emergency plans and the individual's place in the organizational structure. This place in the organizational structure should be identified from the beginning in a new employee orientation and reinforced over time.
3. Self-assessment by workers. Given a set of competencies, individuals should ask. "Am I able to…." and develop personal training plans to meet self-perceived deficits.

Some competencies apply to all public health workers within an organization, but they may be demonstrated in different ways. Others are specific to the individual's profession or place in the organization. The competencies represent levels and layers. Some preparedness competencies are generic; others will be specific to a profession, a program area, or an individual's likelihood of needing that particular competency. Cross-cutting competencies might include communication capabilities, familiarity with applicable law, knowledge of basic epidemiology, and management skills. Of course, the complete set of emergency preparedness and response competencies should include specific bioterrorism response competencies.

The core competencies for public health professionals are the foundation for public health practice. They do not apply to any specific profession or program area, and they vary in depth, depending on the level of responsibility. For example, all public health professionals need to have some level of competency in:

1. Identifying, interpreting, and implementing public health laws, regulations, and policies related to specific programs;

2. Articulating the health, fiscal, administrative, legal, social, and political implications of policies; and
3. Using the legal and political systems to effect change.[4]

Key emergency preparedness competencies include the ability to describe the public health role in emergency response, to describe the individual's role and responsibility during different types of emergencies, to identify the limits of personal knowledge, skills and authority, and to know where to go for additional resources. Leaders, in particular, must be able to communicate public health information, roles, capacities, and legal authority for all emergency response partners.[5]

The Role of Law in a Bioterrorism Response

Law has a critical function in a bioterrorism situation. Knowing how to apply core legal competencies in a bio-terrorism event is a necessity. These public health law competencies represent a set of law-specific skills and legal knowledge desirable for the practice of public health.[6] They serve as guides to workforce development efforts for public health leaders who have specialized roles related to public health law, as well as for front-line staff who need a basic understanding of the role of law in protecting the public's health.

Public health law competencies focus on knowing one's place in the emergency setting. Individuals must be able to (a) apply the meaning, source, and scope of the state's powers, (b) understand the scope of the state's traditional and emergency powers, and (c) distinguish the duties of public health agencies from those of other state, federal, and local public agencies in multiple areas of law, such as criminal law and environmental protection.

In responding to an emergency situation, one should know when to seek legal advice, how to provide factual assistance to legal advisors, how to develop enforcement strategies consistent with the law, and how to apply ethical principles to the development and interpretation of laws.

The specific legal activities associated with a response to bioterrorism or, in fact, to any emergency situation may include

1. Conducting searches of private premises;
2. Seizing or closing private property;
3. Providing and directing treatment or screening;
4. Implementing quarantine, isolation, or other restrictions of movement;
5. Issuing or revoking licenses or permits; and
6. Protecting confidentiality in the collection, maintenance, and release of information.

All these activities require a public health worker to possess the necessary competencies in the nature and application of public health law.

Lessons Learned from the Response of Public Health Organizations to the 2001 Anthrax Emergency

Although the public thinks of only five states as being affected by the anthrax bioterrorism threat in recent months, in reality all of the states were impacted. After all, members of the public from practically every state were afraid of the disease, and they made many requests for testing of both suspicious white powder and possibly infected individuals. In addition, many states developed relationships with the Federal Bureau of Investigation (FBI) as a result of addressing anthrax hoaxes. In Georgia, for example, the FBI set up an office in a state laboratory that tested suspicious powdery substances.

The public health challenge associated with the anthrax threat has helped public health organizations to prepare for the next bioterrorism threat, because these organizations learned a great deal from dealing with the anthrax threat. Among the lessons to be learned from the experience are:

1. Contrary to traditional medical privacy and confidentiality guidelines, public health organizations sometimes need to identify

people to the public. With a suspected case of a communicable disease, such as smallpox, it is important to find out who might have come into contact with the potentially infected individual. It is also important to know when not to breach confidentiality and how to keep the media from putting together minimal information to identify individuals or situations.

2. Public health organizations exercised skills in chain of custody procedures as they dealt with the anthrax emergency. Laboratories and regulatory staff developed these procedures and now practice them on a routine basis.
3. It is essential to know when and how to isolate or quarantine individuals or groups of people. In addition to practicing isolation procedures, public health organizations may need to direct the actions of others, such as requiring a suspected case to take body temperature twice a day. These organizations need a flexible power to control behavior. The public health and the medical community can be challenged with the need to impose restrictions on individuals while also trying to maintain the necessary respect for the individual and his/her rights.
4. Public health organizations must respect the knowledge, skills, and authority of other professions. For example, public health now has a renewed respect for the fire chief, the police officer, the legal system, and other new and old partners.

Bioterrorism Response Preparedness at the Local Level: An Example

The DeKalb County, Georgia police have developed detailed methods for dealing with any potential bioterrorism threat. Part of the preparation for a response has been the development of a Suspicious Materials Protocol, because the police receive up to 30 calls a day about suspicious items and materials. In addition, because certain threats have immediate implications for public health, the police have developed a very strong relationship with public health agencies. The relationship between public health and law enforcement agencies has grown very strong. Both the police and the public health organizations with which they work use evidence control and chain of custody procedures in investigations of cases of suspicious materials.

The current procedure used in DeKalb County is for the Hazardous Materials Team to make the first response to a possible threat. Members of this team bag suspicious materials and call public health organizations. Team members also list all people in the houses or buildings possibly exposed. Public health workers follow up by making contact with the individuals who have been potentially exposed. Law enforcement handles delivery of specimens to public health organizations and provides information to the state health department. Most testing of specimens is done at the state laboratory. DeKalb County uses five detectives to deal with all suspicious material. They have followed the guidelines provided by the Centers for Disease Control and Prevention by bagging suspicious material and keeping it for 60 days in the property room. Law enforcement also works closely with the local board of health and with the state board of health as a means of remaining prepared to deal with any bioterrorism threat.

Conclusion

Preparedness on the front line of emergency response requires public health leaders and administrators to understand their roles and the roles of emergency response partners. These leaders and administrators, as well as their staff, must especially have an understanding of the legal powers of their agencies in addressing a public health emergency event. Finally, public health leaders and administrators must ensure that staff members possess the competencies necessary for an effective and efficient response to bioterrorism and for working with law enforcement personnel and other partners in addressing public health emergencies.

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Immigrant Health: Legal Tools/Legal Barriers

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ABSTRACT

The United States is a country of immigrants, our government having been formed by recent arrivals. This trend has continued throughout our history; according to the Center for Immigration Studies, more than 26 million immigrants have settled in the United States since 1970, and approximately one million new immigrants come to the United States each year. The immigrant population faces highly diverse health issues that states, cities, and counties must address, many of which pose significant legal and policy issues. Social, cultural, and linguistic factors complicate those challenges, as does the overlay of federal immigration and health policy. Two federal laws, the Welfare Reform Act of 1996 and Title VI of the federal Civil Rights Act of 1964, have affected immigrants in two very different ways. The former made it difficult for immigrants to qualify for publicly funded benefits. In contrast, Title VI made it easier for immigrants to obtain benefits by requiring federally funded service providers to offer translating services to persons with limited English language skills. Tuberculosis treatment is perhaps the most pressing health need among recent arrivals to the United States. Methods to slow down and hopefully eliminate this disease are underway, but a more comprehensive approach to not only tuberculosis but to immigrant health in general is needed. Indeed, it will benefit those directly affected by tuberculosis and will have serious implications for the entire population for generations to come.

Does the term *immigrants* refer to someone who arrived here legally to study, to work, or to join family members, or does the term refer to a refugee seeking asylum from a home country, as so many families have done in our country's history? Or, finally, is an immigrant one of the roughly 420,000 people a year who come to America undocumented?[1] These are important distinctions to make as immigrant health issues are raised.

The United States has always been a destination for people from other countries. In the 20th century, immigration peaked in the first couple of decades but was rapidly declining by 1940; it reached an all-time low in 1970.[1] But as laws and national immigration policy began to change in the 1970s, the United States saw an insurgence of both documented and undocumented immigrants and refugees.

During the spring of 2000, 28.4 million immigrants formed 10 percent of the country's total population—the largest number of immigrants in United States history, the highest percentage in 70 years, and a 43 percent increase from 1990. In fact, nearly 1.5 million immigrants—legal and illegal—now settle in the United States each year.[1]

California is a good example of why a state should seriously examine public health as it relates to immigrants. That state has the largest immigrant population in the country, both in terms of numbers and as a percentage of the population (8.7 million immigrants, 26 percent of the population). New York, Florida, Texas, and New Jersey follow California. For comparison's sake, Minnesota is 21st with 243,000 immigrants; Iowa has 110,000; and Nebraska 62,000. Last on the list are Montana and Wyoming, with under

10,000 immigrants and less than one percent of the total population.[1]

A pressing issue and one of the greatest facing immigrants is the general lack of health insurance coverage. One-third of immigrants in the United States do not have health insurance, a ratio two and one-half times higher than for the native-born population.[1] This proportion is largely attributable to the "intimidating" nature of our health care system, made worse by language and cultural differences (i.e., the Hmong traditionally use healing and ceremonies to rid the body of illnesses and would not consider going to a local health care clinic). Certainly, access to health care is made more problematic in rural parts of the country, and poverty only intensifies the situation. Immigrants and their children make up nearly a quarter of all people living in poverty, and the poverty rate for immigrants is 50 percent higher than that of native-born individuals. In addition, immigrants who have arrived in the United States since 1989 and their U.S.-born children make up a majority of the increase in the size of the uninsured population.[1]

Minnesota provides a snapshot of health-related problems common among immigrants. In Minnesota, recent 2000 Census data show that in 1999, 5.3 percent of the state's population was foreign born. Of that proportion, 40 percent came from Asia, 24 percent from Latin America, and 13.2 percent from Africa.[2] In the Twin Cities, one needs only to walk down a major thoroughfare to see the Hmong and Somali-owned businesses sprouting up and adding new life to the community.

Refugees also provide a good snapshot of immigrant health. With few exceptions, the average number of refugees coming to Minnesota each year has hovered between 1,500 and 2,500 (although Minnesota had 4,000 refugees arrive in 1999). Also, Laotian, Hmong, Cambodian, and Vietnamese refugees have all but stopped arriving in Minnesota in the last few years, but immigrants from former Soviet Union states and Africa, largely from Somalia, Ethiopia and Liberia, have been increasing (i.e., 287 Somali refugees arrived in Minnesota in 1998, and 1,443 the following year).[3]

Refugee arrivals have dropped off significantly since 9/11, both nationally and in Minnesota. Last year, 2,800 refugees arrived in Minnesota, but only 85 between October and December (oral communication with A. O'Fallon, Minnesota Department of Health, June 2002). The health and well being of these refugees are reflective of the substandard conditions found in refugee camps. Tuberculosis is one of the most prevalent diseases among refugees: 80 percent of new cases in Minnesota are from refugees, up nearly 100 percent from ten years ago. In addition, as refugees assimilate into the population and begin dealing with the hardships of being poor in America, increases in heart disease and diabetes become more common (oral communication with A. O'Fallon, Minnesota Department of Health, June 2002). Although refugees are screened and treated for infectious diseases in the first eight months they are here, after that they are generally left to fend for themselves. Minnesota has an exceptionally high rate of health insurance coverage, with only five percent of Minnesotans uncovered. However, for foreign-born individuals, the situation is much different. Thirty six percent of those from a Hispanic nation are without health insurance, twenty five percent from African nations, and seven percent from Asian nations.[4]

Major Health Issues Affecting Mexican Immigrant Communities

In the United States, foreign-born residents represent 10% (26 million) of our population, and currently over half come from Latin America and one quarter from Asia. Approximately 80 percent of them are here legally to pursue the same American dream that spurred earlier waves of immigration.

An examination of the health of Mexican and Latin American immigrants raises many concerns among the public health community. This is doubly true in the case of undocumented immigrants. This group is growing by 275,000 persons every year. Such undocumented immigrants are often forced to seek out employment in hazardous occupations like ranching, agriculture, and construction. Many view

entry into the United States as part of their "life destiny." They undertake this journey frequently over the span of their young adult years, often at considerable risk to their personal safety. Not all of these refugees are necessarily planning to become permanent residents; rather, many desire only access to employment opportunities that will support their families who remain at home.

These circumstances raise many public health concerns. For instance, undocumented workers have limited and inconsistent access to health care. They have no protection or compensation from work-related injuries. Employers frequently pressure them to leave the job and return home in the event of their illness or disability. They are often not immunized against serious diseases (e.g., rubella) and pose a threat of importation of communicable diseases (e.g., tuberculosis) that can easily spread throughout our communities. It is common for the population of young, single, or unattached males to engage in risk-taking behaviors (e.g., multiple sexual partners, drug/alcohol abuse, etc.). In those cases in which an undocumented worker has a family accompanying him, other complications create health consequences. For example, fear of deportation as illegal aliens forces many parents to forgo necessary health care for their children or to delay getting prenatal care. Also, cases of adolescent boys and girls who are sexually abused by adults in the United States side of the border are on the increase because these young people often fear the consequences of reporting the abuse. The fact that undocumented or illegal aliens are ineligible for state and local public assistance compounds the health problems. While health care providers may offer treatment for emergency medical conditions, they withhold even the most basic preventive services.

More must be done to encourage bi-national collaboration on these and other health issues. Foreign governments must warn their citizens of the risks involved in illegal entry into the United States. Title V funding needs to be expanded to support early prenatal care for undocumented women. Efforts must be increased to address sentinel conditions dealing with childhood and adult immunizations, infectious diseases, and worker safety. Public health and border security personnel need to coordinate efforts more effectively—for example, current guidelines dealing with informed consent, quarantine, and deportation need to be reviewed and updated to provide better protection for both immigrants and members of the host communities.

How Laws Directly and Indirectly Affect Immigrants' (and the Public's) Health

Two federal laws that originally were enacted to address policy concerns other than public health have nevertheless directly and indirectly affected immigrants' access to health care and the public's health. One of the laws creates formidable barriers, while the other provides the tools for improving immigrant health. The Welfare Reform Act of 1996 erected barriers to services for most immigrants by severely restricting immigrants' eligibility for publicly funded benefits. In contrast, Title VI of the federal Civil Rights Act of 1964 removes barriers by requiring service providers that receive federal funding to offer language assistance to limited-English proficient persons, who are often (but not always) immigrants.

The Welfare Reform Act of 1996

In 1996, Congress enacted the Personal Responsibility and Work Opportunity Reconciliation Act, more commonly known as the Welfare Reform Act.[5] In addition to making dramatic changes to public assistance programs, the Act imposes new restrictions on immigrants' eligibility for publicly funded benefits and services. The Act states that it is the policy of the United States that "aliens within the Nation's borders not depend on public resources to meet their needs, but rather rely on their own capabilities and the resources of their families, their sponsors, and private organizations."[6] In accordance with that policy statement, Congress wrote provisions into the law that restricted benefit eligibility for all immigrants in the United States—those who are authorized (or documented) as well as those who are not.

The Welfare Reform Act created the designation "qualified alien" to distinguish between immigrants for the purpose of determining benefit eligibility. The term is not used in any other area of the law. A "qualified alien" is a person who is not a United States citizen or a U.S. national and who fits into one of the following categories: lawful permanent residents, refugees, persons granted asylum, persons granted withholding of deportation, Cuban/Haitian entrants, Amerasians, persons paroled into the United States for at least one year, noncitizens present in the United States since before April 1 1980, conditional entrants, and some battered spouses and children.[a] The Act did not create a term for immigrants who are not qualified aliens, but the term "nonqualified aliens" has been commonly used to describe such immigrants. Nonqualified aliens include not only undocumented immigrants, but also significant categories of noncitizens who are lawfully in the United States, such as applicants for asylum, persons residing under color of law, and nonimmigrants (e.g., students, tourists, or business travelers).

The general rules for benefit eligibility under the Welfare Reform Act are as follows:

1. Most qualified aliens as well as nonqualified aliens are *ineligible* for Supplemental Security Income (SSI). There are exceptions for some groups of qualified aliens: those who have long work histories in the United States (forty or more qualifying quarters under the Social Security Act); those who have military connections (active duty, veterans, and some others); and some disabled persons, elderly persons, and children who were legally present in the United States on August 22 1996—the date the Welfare Reform Act became law. A limited exception for qualified aliens who were admitted to the United States for humanitarian reasons (refugees, asylees, and some others) permits those individuals to receive SSI for up to seven years.
2. The Welfare Reform Act also made most qualified as well as nonqualified aliens ineligible for food stamps. Subsequent laws eroded this provision, and food stamp eligibility was recently restored for most qualified aliens.[b]
3. Qualified aliens admitted to the United States after August 22, 1996 must observe a five-year waiting period before they are eligible for "federal means-tested public benefits." There is an exception to the waiting period for qualified aliens who have long work histories in the U.S. or military connections, or who were admitted for humanitarian reasons. The Welfare Reform Act did not define federal means-tested public benefits, but federal agencies have interpreted the law to include several significant benefits, such as Medicaid, the State Children's Health Insurance Programs, and Temporary Assistance to Needy Families.[c]
4. Nonqualified aliens are generally *ineligible* for federal, state, and local public benefits—meaning essentially benefits or services that are publicly funded.[d]

However, nonqualified aliens retain eligibility for some significant public health services,including communicable disease services and immunizations, federally funded prenatal care and family planning, emergency medical services and emergency Medicaid, the WIC program, and some mental health and substance abuse services.[e]

The Welfare Reform Act created substantial direct barriers as well as indirect barriers to health care and other health-promoting services for many immigrants. Eligibility is extremely difficult for immigrants to understand, and it is easy to imagine a number of scenarios in which misunderstanding would result in services not being provided (e.g., an immigrant mother may assume that since she is ineligible for Medicaid, her citizen child is also ineligible-an incorrect assumption). Regrettably, service providers sometimes misunderstand eligibility and offer inaccurate information to immigrants as a result. Immigrants may also be reluctant to apply for benefits or serv-

ices for which they are eligible, if they fear being designated a "public charge," or if they are undocumented and fear that applying for a benefit such as emergency Medicaid would reveal their undocumented status to authorities. They may also be concerned about their sponsors' becoming liable for the cost of any benefits provided to them.

The consequences of the barriers to services are many. When immigrants do not receive health services, not only does individual health suffer, but the public health may be impaired as well. For example, there have been several rubella outbreaks in the United States that mostly affected immigrant Latino populations who were unimmunized.[7,8] These outbreaks may be mainly attributable to the immunization policies of the immigrants' countries of origin; still, if an immigrant believes that he is ineligible to receive services at a health department, or if he has been advised not to seek services from any government agency in order to avoid the public charge designation, it may be difficult for public health officials to reach him and provide the immunization or obtain the information that could help curtail an outbreak. An additional barrier to services is thus erected, with potentially serious consequences for public health.

Denying benefits to immigrants also affects the public health in a less obvious way—by straining public health resources and potentially causing agencies to cut back on services. For example, in North Carolina, local public health departments traditionally have depended upon Medicaid reimbursement to support the infrastructure that allows them to provide uncompensated care and supportive services such as health education. Anecdotal reports indicate that uncompensated caseloads in some local health department clinics—especially prenatal clinics—have grown dramatically and are comprised largely of immigrants who are eligible to receive services but are ineligible for Medicaid and unable to pay on their own. In the worst cases, the local health departments are considering closing their clinics.

Title VI of the Civil Rights Act: Linguistic Access

Title VI of the federal Civil Rights Act of 1964 requires health care providers who receive federal funding to offer language assistance to their limited-English proficient (LEP) clients.[f]

Title VI prohibits programs and activities that receive federal funding from discriminating on the basis of race, color, or national origin.[9] While this law by its terms prohibits only intentional discrimination, the regulations implementing Title VI make clear that practices or policies that have a disparate impact based on race, color, or national origin are also prohibited.[10] Neither Title VI nor its implementing regulations expressly address language assistance; however, the U.S. Supreme Court has held that failure to provide language assistance to limited-English proficient persons violated the Title VI regulations when the failure had a disparate impact on a particular national origin group.[11]

The federal Department of Health and Human Services (HHS), Office for Civil Rights (OCR), enforces this requirement. The requirement exists for public health and social services agencies, as well as for any other service provider that accepts Medicaid, Medicare, or that receives other direct or indirect financial assistance from HHS. OCR requires providers to offer oral interpretation services to all LEP clients, written translation of important documents in some cases, and notice to all LEP clients of the availability of language assistance. OCR prohibits providers from charging clients for these services.[12]

Title VI and its implementing regulations reflect a federal policy of prohibiting invidious discrimination. This is not explicitly a public health policy choice, but it clearly has positive implications for immigrant health, as it removes barriers to health care and health-promoting services.

Issues Concerning Completion of Tuberculosis Treatment for Persons in Custody of the Immigration and Naturalization Service

To reduce the risk of exporting and probably re-importing persons with active tuberculosis identified while in INS custody, the federal Advisory Council for the Elimination of Tuberculosis passed a resolution at its February 6, 2002 meeting recommending that the Departments of Health and Human Services and Justice form an interagency policy group, to include key organizations and entities that would work toward a consensus on the following:

1. Exploring the feasibility of treating INS detainees in the United States in the least restrictive setting until TB is cured. Consideration should be given to revising or amending current policies or federal laws for detainees who are being evaluated or receiving treatment for active TB and, to allow deportation only after the responsible state TB controller (or the designate) reviews and approves the treatment plan. For cases of multidrug-resistant TB, the availability of drugs needed to complete treatment in the country of origin should be assured prior to deportation.
2. Working with professional correctional associations to improve adherence to local public health laws and CDC guidelines for TB screening and case notification, and to develop collaboration among the INS service processing center, contract facilities, and TB programs. Protocols should require the sharing of medical information and describe mechanisms for the transfer of care when a patient is deported or released back to the community.
3. Developing policies requiring the reporting of TB cases and TB suspects in INS custody prior to the transfer or deportation of an INS detainee with active or suspected TB to the Division of Immigration Health Services and state and local TB control programs of the jurisdictions where the sending and receiving correctional facilities are located.
4. Expanding the medical hold authority of the DIHS medical officers to permit notification of receiving health care providers or use of a national referral program (e.g., CURE-TB or TBNet), including permitting the transfer of medical records and provision of sufficient TB medications to ensure treatment until the patient's care is complete.

Conclusion

It will take a broad coalition of organizations and creative solutions to "solve" the health care access problem for immigrants. A large piece of the puzzle is simply reaching out to immigrant and refugee communities and letting them know that services and programs exist.

As the gap closes between immigrant health and the rest of the population, it will become apparent that physical health is just the tip of the iceberg. Mental health and chemical dependency are the next, and equally important, health issue that must be addressed. Additionally, the United States population needs to grow in its realization that providing for basic public health safeguards for this at-risk population is not merely a humanitarian gesture but also enlightened self-interest.

The opinions and findings in this article are those of the authors and should not be construed as representative of agency policy.

ENDNOTES

a. Certain battered spouses and children were added to the definition of qualified alien by the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, Pub. L. No. 104-208, 110 Stat. 300a (codified in scattered sections of 8 U.S.C.)

b. The Agricultural Research, Extension and Education Reform Act of 1998, Pub. L. No. 105-185, 112 Stat. 523, restored food stamp eligibility for children, adults over the age of 65, and disabled adults who were lawfully present in the United States before August 22, 1996 (the date the Welfare Reform Act was enacted). The Farm Security and Rural Investment Act of 2002 restored food stamp eligibility for most qualified aliens (H.R. 2646 § 4404, signed by the President on May 13, 2002.) In most cases the individual must have lived continuously in the United States as a qualified alien for five years.

c. See, e.g., Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA): Interpretation of "Federal Means-Tested Public Benefit," 62 Fed. Reg. 45256 (Aug. 26, 1997) (interpretation of the U.S. Department of Health and Human Services.)

d. The term "federal public benefit" is defined as follows:

(A) any grant, contract, loan, professional license, or commercial license provided by an agency of the United States or by appropriated funds of the United States; and

(B) any retirement, welfare, health, disability, public or assisted housing, postsecondary education, food assistance, unemployment benefit or any other similar benefit for which payments or assistance are provided to an individual, household, or family eligibility unit by an agency of the United States or appropriated funds of the United States.

Pub. L. No. 104-193, § 401(c)(1). Part A of the definition does not apply to the employment-related contracts or licenses of nonimmigrants whose entry visas are related to their employment in the United States. *Id.* § 401(c)(2). The definition of "state and local public benefits" parallels the definition of federal public benefits, except that the benefits are supported by state or local funds instead of federal funds. Id. § 411(c).

e. Eligibility for these benefits is found in several sources. Some are listed in the Welfare Reform Act itself. See Pub. L. No. 104-193, §§ 401(b) and 742. Others are derived from a Federal Register notice published by the U.S. Department of Justice in August 1996, and others from an interpretation of the term "federal public benefit" that was published by the U.S. Department of Health and Human Services in August 1998. See Specification of Community Programs Necessary for Protection of Life or Safety under Welfare Reform Legislation, 61 Fed. Reg. 45,985 (Aug. 30, 1996); Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA; Interpretation of "Federal Public Benefit," 63 Fed. Reg. 41,657 (Aug. 4, 1998).

f. In 2001, the Supreme Court decided a case that involved a state's policy of providing driver license examinations only in English. Alexander v. Sandoval, 532 U.S. 275 (2001). Ms. Sandoval sued the state, claiming that its policy violated the Title VI regulations. The Court ruled that individuals may not bring such suits. However, the Court did *not* overrule *Lau* or invalidate the Title VI regulations from which the language assistance requirements are derived. Although individuals may no longer sue to enforce the regulations, OCR may still enforce them and it has continued to do so. For example, OCR conducted a compliance review of North Carolina's Department of Health and Human Services and issued a letter of findings in May 2002. Letter of Roosevelt Freeman, Regional Manager, U.S. DHHS Region IV Office for Civil Rights, to Carmen Hooker Odom, N.C. Secretary of Health and Human Services, May 24, 2002 (Ref. Docket No. 04-01-7002) (on file with author).

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The Dimensions of Public Health Law Research

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ABSTRACT

Applied public health law research is an essential element for improving the legal foundation of public health practice. This article focuses on the proper scope and the methodology related to conducting public health law research. In addition to considering the issue of translating research into practice, the article provides overviews of three current public health law research projects and the lessons they provide for researchers.

Public health law research is a multi-disciplinary approach to improving the legal foundation of public health. Public health law has been defined as the "legal powers and duties of the state to assure the conditions for people to be healthy ... and the limitations on the power of the state to constrain the autonomy, privacy, liberty, proprietary, or other legally protected interests of individuals for the protection or promotion of community health."[1] As such, public health law is generally considered to include not only those laws authorizing public health agencies and programs (such as laws authorizing a local public health agency to conduct surveillance of infectious diseases), but also laws that authorize specific health interventions, as in a statute mandating the use of car seats for infants. The field of public health law is now also increasingly understood as embracing inquiry into how law may operate as a structural determinant of population health.[2]

This article attempts to provide some tentative answers to three questions relating to public health law research:

1. What is the appropriate scope of public health law research?
2. What methods should public health law researchers employ?
3. How can public health law research be translated into practice?

Summaries of three public health law research projects now underway provide some indication not only of the scope and methods, but also of the challenges that researchers confront in studying, working with, and/or implementing public health law.

The Scope of Public Health Law Research

The process of determining the proper scope of public health law research begins with defining the purpose of the research. The three primary purposes of public health law research are to (a) influence policy, (b) improve the use of law as a public health tool, and (c) better understand law as a social determinant of health. The scope of such research should be broad enough to include systemic data collection and analysis in the following domains:

1. Epidemiology. This area includes examining the effects of laws and legal practices on

public health outcomes such as morbidity and mortality as well as the law's influence on health behavior and other risk factors.
2. Legal doctrine. This area incorporates an examination of laws in a specific health-related area, the meaning of the laws, and their degree of consistency with applicable legal standards such as constitutions.
3. Legal practice. This area looks at how laws are enforced and the factors that influence the passage or implementation of laws.
4. Social and ethical questions. The scope of public health law research includes examining the ethical implications of a public health law and whose interests the law serves.

The existing architecture of public health systems serves as a constraint on the scope of public health law research to the extent that such research typically occurs within and pursues the interests of actual operations of public health organizations. In particular, public health law research follows an interdisciplinary approach that is as broad as the operations and mission of public health practice itself. The scope of public health law research includes pursuing answers to such questions as:

1. What causes public health policy to become law?
2. Why does policy become law in some environments and not in others?
3. What motivates policy makers to create or not create laws that address public health concerns?

Public health law research, if it is to be effective, should be tied closely to both public health practice and public health policy, both informing and being shaped by them.

Methods for Conducting Public Health Law Research

The methodology of public health law research encompasses several activities, including:

1. quantitative and qualitative data collection and analysis (primarily for epidemiologic public health law research);
2. legal and historical research and analysis (often used for research of legal doctrines);
3. social science data collection and analysis (generally used for research of legal practice); and
4. consideration of bioethics, legal scholarship, and social science (often used when researching social and ethical questions.)

Regardless of the methodology pursued, public health law researchers need to focus on both the socio-cultural dimensions of a project and the importance of communication as a means of conveying the findings to public health practitioners as well as to lawmakers and the general public.

The Socio-Cultural Dimensions of Public Health Law Research

It is important for researchers to acknowledge the cultural gap between the practitioners who help create public health policy and the lawmakers who create new policies in law. There is a distinction between evidence for scientific or health research and the evidence for legal research. While lawyers may think of evidence as what is permitted by the Federal Rules of Evidence or other accepted rules of a court, practitioners generally consider evidence as scientific findings in the form of precise and rigorously collected data that is systematic and reproducible. In short, lawmakers and practitioners think differently, and communication between the two sides is therefore essential. Because of this gap, public health practitioners should receive some basic law-related training; similarly, lawyers who advise these practitioners should be trained in the basics of public health.

It is well accepted in both the legal and the public health communities that socio-economic status, education, and other social factors are predictors of the health of individuals. It is therefore important that public health practitioners recognize that law may be considered a social determinant of health, affecting socio-economic

status and income inequality, attitudes toward race and racism, community and social organization, and specifically social capital and social cohesion. Accordingly, public health law research methods need to incorporate social science methods and theory as part of the multidisciplinary approach to studying public health law.

Communicating the Results of Public Health Law Research

An effective communications plan is an integral part of establishing a public health law research methodology. If the results of the research cannot be communicated and made understandable and accessible to public health practitioners, lawmakers, and members of the public, it is unlikely to become part of public health policy, to gain acceptance by lawmakers who have the power to convert policy to law, and to receive public support. For example, while numbers and statistics are helpful in generating the interest of policymakers, they are less effective in getting a law passed. Anecdotes may be more effective in communicating the results to lawmakers. Partnerships between public health practitioners and lawyers may also garner support of lawmakers for a new public health law. Gaining the support of the general public for a policy based on research findings may require the use of television or other paid media and spokespersons assigned to meet with public groups.

Examples of Current Public Health Law Research Activities

For public health law research to thrive, it must be supported by a reliable funding stream. The Centers for Disease Control and Prevention currently funds eight peer-reviewed public health law research projects. A brief overview of three of these projects follows.

The Impact of New York's HIV Reporting and Notification Law

The reporting of HIV test results has been a controversial policy issue for well over a decade. Proponents of reporting such testing have pointed to its value as a surveillance tool. Opponents have argued that reporting test results, particularly by name, to local or state authorities will deter those at risk of HIV infection from being tested.[3–5] The state of New York became the 33rd state to include HIV as a reportable condition with passage of the HIV Reporting and Partner Notification Law (HIVRPN), which took effect June 1, 2000. The state thereby became the first state in the nation to specifically integrate in statute partner notification with the reporting process. The law requires reporting of persons with HIV infection in addition to persons with AIDS who were previously reported, as well as sexual and needle-sharing partners of HIV/AIDS patients known to the medical provider, and, at the discretion of the responsible health official, ensuring that these persons are notified of their possible exposure.

The AIDS Institute of the New York State Department of Health is presently undertaking a three-year research project designed to assess the impact that the law has on New York's ability to effectively conduct public health surveillance of HIV infection and its impact on the willingness of individuals to be tested. Researchers have analyzed data collected as part of the New York State HIV/AIDS Surveillance and Partner Notification System. The research methods have included (a) characterizing HIV/AIDS data collected; (b) consulting focus groups consisting of consumers and providers; (c) administering an HIV Testing Survey (HITS) to high risk groups; and (d) surveying HIV counseling and testing providers in New York State.

Some of the project design lessons learned during this research project are (a) the value of using multiple methodologies, study populations, and data sources; and (b) the usefulness of anecdotal information to suggest research questions and to communicate test research findings.

Lessons learned related to the law itself include the need to:

1. seek input from affected groups. Project members met with many groups representing a broad spectrum of interested parties,

including persons with HIV, advocates, key community leaders, county health departments, and other state agencies.
2. be responsive to input from the public. Project members used solicited public comment to strengthen confidentiality provisions of the law as implemented.
3. maintain good communication with all parties during the research process. Project members undertook mass mailings to a large interested parties' list several times to keep these parties updated and to provide copies of draft regulations for comment. Project members also posted information on the Web and discussed it at routine program meetings as a means of keeping people aware of developments and avoiding unfounded rumors.
4. give adequate lead time to ensure sound education, training, and program implementation. For example, the final regulations were published three months before they took effect in order to provide adequate time to get the program ready, to conduct training, to distribute educational materials, and to develop secure computer systems to protect data.
5. conduct widespread educational and training sessions to inform those who will implement the regulations. Project staff conducted several video conferences to educate physicians, state staff, and others about the regulations. The staff also developed and widely disseminated protocols, guidelines, and other materials. In addition, materials were translated into several languages, and staff conducted several training sessions directed toward trainers who would be involved in preparing providers and others to follow the regulations.
6. monitor the implementation process. All program staff, including the staff lawyer, attended weekly two-hour meetings for the first several months after the effective date of the regulations in order to share information about implementation progress.
7. involve the legal staff in all programmatic development meetings. Legal staff members can provide valuable advice.

Research to Evaluate the Effectiveness of Washington's State Ergonomics Rule

Of increasing concern in recent years has been the prevalence of work-related musculoskeletal disorders (WMSDs) among workers. Such disorders, including carpal tunnel syndrome, account for millions of hours of lost productivity and large outlays in medical expenses throughout the United States.

In response to the problem, Washington State promulgated an ergonomics rule designed to reduce and eliminate exposures of workers to conditions associated with WMSDs in the workplace in May 2000, with a six-year phase-in period based on industry hazard level and company size. The Washington State Department of Labor is currently engaged in a research projectdesigned to gauge the effectiveness of the rule. The project is evaluating (a) employer awareness of workplace risk factors and prevention activities; (b) any reduction in the amount of time required to identify and reduce hazardous exposures; and (c) the effect of the ergonomics rule on the rate of worker compensation claims filed by workers with WMSDs, as compared to claims in states without such a rule. The methodologies employed in the project include conducting employer surveys and making site visits to gauge increases in employer awareness of WMSDs and the effects of prevention steps taken.

Lessons learned during this project have included the importance of assessing the scope of the problem, the need to compromise, and the need to gain support from conflicting interest groups, including workers and employers. Examples include (a) using both flexibility for large employers and specificity for small employers in identifying hazards; (b) limiting employee education requirements to those with a certain level of risk rather than for everyone; (c) requiring employee involvement in the identification and control of hazards but not in the initial identification of potentially at-risk jobs; (d) having no record-keeping requirements; and (e) listening carefully for words that take on negative symbolism and substituting less symbolic words.

Research on the Impact of Law on Core Public Health Functions

State statutes support many of the core functions of public health practice. However, sometimes it is difficult to determine whether such statues achieve their intended effects or whether, in fact, they impede effective public health practice in some respects.

The George Washington University School of Public Health and Health Services is currently undertaking a research project designed to examine the extent to which law influences the ability of public health agencies to carry out core public health functions. One area of this research focuses on whether state laws are achieving their intended effect to improve the oral health of low-income children. The researchers' methods include collecting and analyzing state statues and regulations and conducting case studies that compare dental practice laws.

Among the lessons learned during this research project is the value of applying health services research techniques to public health law research.

Conclusion

Effective public health law research requires an understanding of its multidisciplinary nature, its primary purposes, and its relationship to public health practice and policy. The methodology of such research encompasses several activities, including quantitative and qualitative data collection and analysis, legal research and analysis, social science data collection and analysis, and recognition of the place of bioethics, legal scholarship, and social science in a research project. Public health law research also requires researchers to recognize and address the socio-cultural dimensions of public health law and to develop a communication plan that will convey findings in the most effective manner to public health practitioners and policy makers, to lawmakers who translate public health policy to law, and to members of the general public. Finally, an ongoing funding mechanism is an essential element to ensure the continuing vitality of public health law research.

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The Future of Public Health Preparedness

Sam Nunn

ABSTRACT

This redacted version of a speech by former United States Senator Sam Nunn, Chairman of the Nuclear Threat Initiative, points out that although there are concerns about global issues involving security and weapons of mass destruction and bioterrorism, it was not until September 11, 2001, that these issues (and new, unforeseen ones) were getting the funding and attention they deserved. In the event of a biological attack, millions of lives may depend on how quickly we diagnose the effects, report the findings, disseminate information to the healthcare communities and to state and local governments, and bring forth a fast and an effective response at the local, state, and federal levels. Public health must become an indispensable pillar of our national security framework. As we develop a national strategy to respond to these challenges, we must think in the broader context of causes as well as symptoms. To provide context for the next 25 years, Senator Nunn provided an overview of the "Seven Revolutions" for change identified by the Center for Strategic and International Studies (CSIS) with which he is also associated. Finally, he discusses major security challenges facing the United States.

First, I want to thank all the people at this conference who have been engaged in the application of our laws and our legal system to the public health arena. I know you come from diversified backgrounds, including state and local officials, state legislators, government attorneys, academicians, and people who are engaged in the public health service. So I'm grateful to have a chance to be with you, and I think your subject is not only timely, but is one that is crucial for our nation.

This conference involves discussing laws and their application to public policy. I am going to cast a rather broad net and discuss some of the security background and some international and global developments.

Even though I retired from the Senate about five years ago, I have remained involved, engaged, and very interested in public policy. For many years, I have believed that keeping weapons of mass destruction, whether nuclear, chemical or biological, out of the hands of terrorists groups—dangerous people who would not hesitate to use them—was our number one security challenge. I came to that conclusion in the early 1990s, and that is why I introduced the Nunn-Lugar legislation in 1991, joined by Dick Lugar. And that is why I worked not only for its passage in that year, but also for a successful implementation for the last ten years.

I also introduced the Nunn-Lugar-Domenici legislation in 1996, and I worked for its passage and implementation with Senator Lugar, Senator Domenici, and others. The latter legislation was an effort, and continues to be an effort, to help our local and state governments prepare for what I felt was inevitably something we had to prepare for, and that is nuclear, chemical, and biological attacks on our citizens.

Now I am dedicating about 50 percent of my time to a foundation that is generously funded by Ted Turner, which addresses nuclear, chemical

and biological proliferation, and the public policy issues associated with these concerns. We know that government has to do the heavy lifting, but we are trying to fill the gap between a huge threat and the governmental response, not only in this country, but across the globe. We have an outstanding group of directors and trustees that come from not only America, but India and Pakistan, as well as China and Japan, and from Russia and Europe.

I am not an expert in public health but I do know a little bit about security, and I know that we have to recognize today something we have not recognized in the past. Public health must become an indispensable pillar of our national security framework. It can no longer be separate and apart. We have to link public health and national security as we have never done before. In the event of a biological attack, millions of lives may depend on how quickly we diagnose the effects, report the findings, disseminate information to the health-care communities and to state and local governments, and bring forth a fast and an effective response at the local, state, and federal levels. This means that public health and the medical professions must be part of our national security team.

The good news from the biological terrorism front (and there is not much here in the way of good news, but it is news to most of the American people and, indeed, to most in government) is that in our global society, most things we now must do because of the threat of biological terrorism also help us prevent and respond to infectious diseases, which now take the lives of millions of people per year.

So I think these two subjects are joined together now. Perhaps we can find common ground in the foreign policy area in terms of helping people in distressed nations that will ring a bell with the American people, and connect benevolence and our moral obligation to help address infectious diseases with our own security concerns here at home, because the two are, indeed, linked. I believe that as we develop a national strategy to respond to these challenges, we must think in the broader context and think in terms of how the public health and biological challenges fit into the overall context in terms of not just immediate symptoms and immediate concerns, but also the underlying causes.

I am the Chair of the Center for Strategic and International Studies (CSIS), and we have developed over a period of time a presentation called the "Seven Revolutions." The Seven Revolutions is a challenge to leaders—a challenge to think seriously about events that are over the horizon, and a challenge to formulate near-term policies that take into account longer-range consequences—something we are not very good at in the public arena. We must look at not just America, but other places. I will describe just a few of these earthshaking developments that are taking place in the world as a way to put our own challenges in context.

First, we are having a revolution in the population of the world. The world population, which is currently at 6.18 billion, will grow by almost 2 billion by the year 2025. By then, 80 percent of the world's population will be in developing countries—in other words, in countries that are least capable of supporting further population growth. This population growth will also present the challenge of what is being termed in this Seven Revolution presentation as "hyper-urbanization." By 2025, the portion of the world's population living in urban areas will increase sharply to nearly 60 percent. That 60 percent will be dominated in large part by young people, and those young people will be primarily unemployed young people with rather bleak futures. Already, up to half of the population in the larger cities in the developing world are living in unplanned squatter colonies, highly susceptible to disease and, indeed, disaster.

Paradoxically, on the other hand, the developed world population is contracting,shrinking. At least 39 countries across the globe, such as Germany, Japan, and Italy, are expected to be substantially smaller in the next 25 years than they are today. Populations in these developed countries are getting older, a development that presents serious challenges to our healthcare system as well as our fiscal policy. It is good news that we

are getting older, but we have got to start thinking through the implications.

We are also having a revolution in resources, a revolution that will become more intense as the years go by. This population growth that I have referred to will also have revolutionary effects on our resource allocation and distribution, including, but not limited to, water, energy, food, and the environment. The most serious resource scarcity in 25 years, CSIS believes, will be water. Populations are growing quickly in a number of geographical areas incapable of providing water to support these growing populations. This has profound geopolitical implications.

On the food front, despite dire predictions, starvation has declined drastically since the end of World War II. America has played a very large role in that. The issue now is whether increases in productivity can keep up with the rises in population. Biotechnology is a wildcard in light of diminishing land and water resources. Stunning technological advances may be possible—probably are possible—but shifts in public attitudes and a great effort in public education will be necessary to avert the serious political problems that bring about severe dislocations.

We are also having a revolution in technology. CSIS believes that there will be several major and simultaneous drivers of revolutionary technological change during the next 25 years, including computation, genomics, nanotechnology, and, of course, the information explosion and the knowledge diffusion that has taken place and continues to take place at unprecedented speeds. Today, we have the technological tools that can be used to clean up our waste dumps, protect our fragile environment, improve our health and longevity, feed, clothe and house our people, and spread knowledge to every American and, indeed, to the entire world. But—and this is a big but—these same technological tools can be used by the bad guys to disrupt our society, terrify our citizens, and kill millions of our people.

We are also having a revolution in information. Advances in technology have expanded information flows, spanned geographies as never before, reduced time lags in communication, and opened unprecedented opportunities. However, these advances also pose considerable dangers. In the past, economists have pointed to three factors of production—land, labor, and capital—which have been the ingredients of productivity for many, many years. In the information economy, all of these, while they will continue to be important, are runner-ups to the new primary factor, and that is knowledge.

We're also having a revolution in time and distance. Advances in technology have not only increased the scope, speed, and efficiency of business operations world-wide, but they have brought down the cost of distance by gradually eliminating the burdens of communication, transportation, language differences, and even time. The result has been a staggering increase in the cross-border flow of goods and services, a flow that has large economic benefits, particularly for the underdeveloped world, but also large security challenges.

The benefits of increased integration apply to developed and developing nations alike. The United Nations Development Program maintains that developing countries have achieved in the last 30 years what the industrialized nations took 100 years to accomplish. Yet, the obstacles to continued economic development are tremendous. A staggering 2.8 billion people live on less than $2 per day in the world; 1.2 billion live on less than $1 per day. The evidence suggests that these income gaps are widening, not closing.

We are also having a revolution in war and conflict. Patterns of conflict are changing. Nation states no longer have a monopoly over super-violence, or what I call catastrophic violence. Moderate militaries must rebuild their capacities to adapt to new threats and handle a wide range of threats that they did not think about five years ago or ten years ago. History will remember September 11, 2001 as the date the world recognized the arrival of what is now known as asymmetrical warfare. The insidious attacks on September 11th represent a quantum leap in the scale of modern terrorism. They brought to our nation and the world the realization that groups

and organizations with the determination to cause great destruction are willing to use weapons of mass effect, including nuclear, radiological, biological, and chemical weapons if they have them or can get them. These dominant trends have powerful implications for our lives and our future. Unfortunately, trends develop rather quickly—at least we notice them rather quickly—but institutions move very slowly.

Neither the United States nor the world is in a position now to meet the threats or capitalize on the opportunities now coming with the changes in our world. We have awakened since September 11th and the anthrax attacks that followed, but we are not yet preparing for them, not, at least, as fast as we must.

Three key challenges converge to pose a major security challenge to our nation and, indeed, the world. First, there is the persistent and growing gap between the developed and developing world—the haves and the have-nots. This gap continues to inflict humiliation, breed resentment, and spark conflicts in many parts of the world. The uneven integration of developing countries into the global economy, the imbalances in population, the growth between rich and poor nations, the severe environmental degradation, the previously mentioned water challenges, the inadequate public health systems, and the shortage of jobs and educational opportunities in the developing world all form a part of this disparity that the world must recognize. There is some debate over whether the disparities are growing, shrinking, or stable, but there is no denying that in our globalized world resulting from the information age, these disparities are easier to see and harder to accept among the millions who experience these disparities on the wrong end.

The second factor is the number of seemingly intractable conflicts that continue to fester around the globe, inciting public outrage, a shared sense of grievance, and even sympathy and support for terrorists in some quarters, which we could not have imagined several years ago. Most notable among these conflicts are the Israeli-Palestinian conflict and the dispute between India and Pakistan over Kashmir, two nuclear-armed countries now. But these ongoing conflicts have global effect, and we have to recognize they have global effect and begin to deal with them as we would anything else that threatens our security and the security of the world. They create deep grievances, which terrorists are very eager and anxious to exploit and, indeed, are exploiting every day.

The third factor, the possession of materials and the know-how to use nuclear, biological, and chemical weapons, is becoming widely available to both rogue states and to terrorists. People have called this the "democratization of weapons of mass destruction." Ordinarily, we in America, at least, think democratization is a very good thing. But democratization in this sense is different. In the political sense, it means giving more people the right and power to vote and choose their leaders. However, democratization in the area of nuclear, biological, and chemical weapons and materials means giving more people the power to find them, build them, and use them for destruction.

When we combine the growing availability of nuclear, biological, and chemical weapons with the growing anger and hatred it would take to use them, we have a much higher probability of catastrophic terrorism with effects that would make September 11th look like a warning shot.

I always have to pause for a moment and explain, particularly to young people, that you should not despair. We've gone through 40 years with the looming threat of a global nuclear war between two super powers. That was something we lived with and handled for a long, long time. So you have to put things in perspective. For a long time, we had a world that was extremely dangerous, but because of that great danger, both superpowers were restrained and we had relative stability. Today, the risk is much less. We do not have that specter of a total annihilation of mankind by a war between the two superpowers looming over us. But we have a much less stable world now. So we're not the first generation to face dangers, and we should not feel sorry for ourselves in that regard. We need to do what our

predecessors did, and we need to recognize the challenges and deal with them.

So, how do we respond? These dangers did not begin on September 11th. Indeed, because of our response since then, they may have receded, but the perception and apprehension of our citizens has grown enormously since September 11th, and weekly warnings by our government add greatly to this anxiety, for better or worse. We must view September 11th not just as a warning shot, but as a wake up call, helping us realize that terrorist capacity for killing is limited only by the power of their weapons, and spurring us to take the sensible steps and the right steps to defend ourselves, our country, and our future, particularly our children's future. The greatest danger in the world today is the threat from nuclear, biological, and chemical weapons. The likeliest uses for these weapons lie in terrorists' hands, people who do not have a return address. We must do all we can to keep the most dangerous weapons and materials out of the hands of the most dangerous people who would not hesitate to use them. That is my top priority. It has been for a decade. And I hope it will become our nation's and the world's top priority. The bottom line is that we are in a new arms race between terrorist efforts to acquire nuclear, biological, and chemical weapons, along with other weapons of mass destruction or disruption, and our efforts to stop them.

To win the race, the United States needs a strategy to secure these weapons and materials immediately, or as soon as possible, on a global basis. That must be our government's highest priority. So far, it is not. There is a huge gap between the threat and the response, and we must close that gap, and I think we must close it soon. On the good news side, we now have an opportunity to make an enormous difference in reducing these threats, based on our new relationship with Russia and the warm Bush/Putin friendship, which is a very firm foundation if it is built upon. But it will wither away quickly if we do not add meat to the bones.

At the Nuclear Threat Initiative, we have identified several urgent actions that we believe should command our nation's focus and shape our priorities. First, we believe the President and the Congress, indeed, our entire nation, must lead, along with Russia—and having Russia a part of it is absolutely crucial. I spent the first 20 years of my career doing everything I could to deter a war with Russia and the Warsaw Pact. I spent the last part of my Senate career and since then telling people that we have a lot more in common with Russia than we realize. And without Russia, we cannot control these weapons and materials, because that's where the huge stockpile is that is not well protected.

Unprotected nuclear, biological, and chemical materials and weapons anywhere are a threat to people everywhere. Unfortunately, there are no global standards to prevent theft. Security varies widely from one country to the next, and America's security is only as strong as the link at the least well-protected site. This means our security depends on each country's safeguarding all of its dangerous materials, including biological, chemical, and nuclear material used in the civilian sector, for instance in medicine, research, or other legitimate private endeavors. What makes this so hard and so challenging is that so much of this material is dangerous but has dual uses, many of them for the benefit of mankind.

Secondly, we must complete rapid security upgrades for all nuclear weapons and materials in the former Soviet Union within two years, and finish comprehensive upgrades within four years. We are not on that course now. It takes less than 20 pounds of plutonium and less than 10 pounds of highly enriched uranium to make a nuclear weapon that would wipe out Atlanta or any other major city, and I mean literally wipe it out. There are over 1,000 tons of plutonium and highly enriched uranium spread across the former Soviet Union, much of it dangerously insecure. Despite ongoing work for the last ten years by the U.S. and Russian governments to secure these materials, at the current pace, this material will not meet what we call minimal security standards for at least eight to ten years or longer unless we make it a top priority and put it right at the top of our list of priorities.

Third, we must insist on accurate accounting and adequate safeguards for United States and Russian tactical nuclear weapons, including reciprocal monitoring. We believe ours are secure now. These are battlefield weapons. They are much smaller than the strategic weapons, but they would still devastate a major city. Tactical or battlefield nuclear weapons have never been covered in arms control agreements. We can only guess at the numbers in each other's inventories. In other words, we do not know how many the Russians have. We do not know where they are. Yet these are the weapons most attractive to terrorists, more valuable to them and more portable and transportable than strategic weapons. Without an accurate inventory, it is impossible to know if one is missing. And if we want the Russians to cooperate on this—and that is essential—then we have got to reciprocate and cooperate with them and, indeed, with the world.

Fourth, we must strengthen efforts to prevent and respond to bioterrorism through an integrated public health, medical care, and research agenda. This agenda should address critical gaps in the public health infrastructure for infectious disease prevention and control. It should provide for preparing medical providers and hospitals to recognize and respond to biological terrorism and to develop new tools for diagnosis, treatment, and prevention of potential disease threats. It should explore new strategies for reducing inappropriate access to dangerous biological materials. The threat of bioterrorism is, in my view, the threat we are least prepared to handle today.

Last summer, well before September 11th, I was given the dubious honor of playing the part of the President of the United States in an exercise called Dark Winter, which simulated a smallpox attack against this country. In my 24 years on the Senate Armed Services Committee, I have seen scenarios, I have seen war games, and I have seen Pentagon plans for almost every type of horror and every type of scenario you can imagine. A biological weapons attack on the United States, however, fits no existing category, particularly if it is an infectious disease attack. To those of us who participated, the Dark Winter exercise taught us two unforgettable lessons: (1) public health, as I mentioned, is a national security issue; and (2) we were not, and still are not, prepared to prevent or respond to a biological attack on the United States.

During this exercise acting as members of our simulated National Security Council (a number of the participants had actually served in high government posts), we came to realize several important concepts. Our country: had not ranked fighting biological terrorism or infectious disease as high national priorities, had not prepared governmental officials to cope with this new type of security crisis, had not invested enough in the planning and exercises that are absolutely essential for emergency response (it is too late when an emergency happens to practice your plans, they must be practiced in advance), had not ensured that the public health infrastructure was adequate with built-in surge capability, had not educated the American people or developed strategies to constructively engage the media in educating the public about what was happening and what to do (and that is what every family wants to know, what do I do and what is happening?), had not practiced what few plans were in place, and had not produced sufficient vaccine to protect Americans from the disease with which we were dealing. Much has been done since last fall, but there is a great deal more that needs to be done. The exercise Dark Winter underscored the critical importance to our government of communicating, of being accessible, of providing credible information, and of being honest about what our government knows and what it does not know-because if you are not honest at the beginning, you will lose credibility very rapidly.

My personal education continued after the Dark Winter exercise in the summer of 2001. Weeks before September 11th, I wrote an opinion article describing the dangers of an attack and the urgent need for more public attention, and I offered the piece to a major U.S. magazine. They told us there really was not much interest in this subject and it was not timely, so they turned it down.

In October, anthrax letters were mailed to the Capitol Building and other places. Most of the lessons learned in our tragic war game became tragic reality a few months later with the anthrax attacks.

With all of this, what about public health preparedness? Attention is engaged now and a large amount of money has been appropriated. We need to make sure it is spent in the right places on the right priorities. We now have an opportunity to take a series of strong measures to prevent and also prepare for a bioterror attack and infectious disease outbreak-those two go together. Leadership must come from the government, but the private sector has an absolutely crucial and indispensable role in this arena. Specifically, we must have members of the public health, medical, and scientific communities as members of the national security team. The Administration's top public health officials should not have to ask directions to the White House Situation Room if there is a biological attack.

We must strengthen our surveillance systems and extend them worldwide, something that, again, requires a global alliance. America cannot do this alone. We must integrate medical life science capabilities into our intelligence community, and that is not the case now. Our intelligence community must know a lot more about health, and our health officials must know more about intelligence.

We must provide our public health laboratories with the equipment and training they need to quickly identify agents and diseases. We must take advantage of the strides being made to improve communications. That has already started, but we need to put a top priority on it so that we can quickly share crucial information at all levels.

We must continue to make research a priority, even accelerate it, and develop new vaccines, new therapeutic drugs, and new and rapid diagnostic tests. Here is another place that we need to work with Russia. During the period of the Cold War, when we were not supposed to be building offensive biological weapons by treaty, the Soviets were cheating, and they were building those weapons in that capacity. I just toured some of those facilities. They do not readily admit it now, but one of the crucial priorities we have to have, is engage those biological scientists in something that will provide enough food so they can feed their families. The last thing we want, notwithstanding past history, is for those scientists, who not only know how to make smallpox and anthrax, but also know how to make smallpox and anthrax that is already resistant to our current capabilities with vaccines and drugs, to be working for terrorists. We need them in the tent working with us. That is absolutely essential. Some of it is being done, but not nearly enough and when I say "we," I mean not just the United States, but also our friends around the world. That is absolutely crucial.

We must increase surge capability in our healthcare system in general, and our hospitals specifically, which means careful planning in advance, and at least tabletop exercises to show that we have done it-we've been able to do it.

We must keep the recent focus on building our national pharmaceutical stockpile, including rapid production capability for drugs and vaccines, with the highest standards of security for stockpile, storage, and dispersal sites. We must not fall victim to a twin attack that releases a bio-agent and simultaneously destroys our drugs and our vaccines.

We must develop a clear plan for working with the media to provide timely and accurate information to help save lives and prevent panic. We must practice this plan and other plans before emergencies.

We must modernize our legal framework, so that we are prepared to address issues such as epidemic control measures and the appropriate balance with civil liberties. These laws vary from state to state, and many are antiquated. We need to make sure that they are up to date and consistent with our current social values, priorities, and the threats. We need to reacquaint public health officials in all areas of response with the specific authorities these laws provide in advance, and how they can also implement them in advance.

Finally, we must encourage members of the scientific community, as well as the private sector,

to confront the sinister side of modern biological research and development, and to design a system of self policing, best security practices, and safety peer reviews that assure that our technological advances, designed to improve and save lives, are not turned into mechanisms for mass murder. This is absolutely essential.

This responsibility of blocking the misuse of dangerous biological materials is a special responsibility of the research community, and it is based on a principle fundamental to the whole public health exercise, prevention. Notwithstanding all the brilliant medical interventions that treat and cure diseases, nothing is better or cheaper or more timely than prevention. The same is true with terrorism.

No method of consequence management, no matter how brilliant—and we must do a lot of it—is preferable to prevention. We must focus our efforts on preventing a terrorist strike from happening in the first place. This means keeping dangerous materials out of the hands of the world's most dangerous people. And this will require, as I have mentioned, a worldwide effort by governments and the private sector. Even if these efforts are not completely successful and a biological attack occurs, the focus of our preparation should still be on prevention-by early diagnosis, by quick response, and by preventing its spread so as to prevent it from taking one more life than it absolutely must.

Finally, funding new health initiatives is difficult. When budgets get tight, public health in years past was often left behind. The threat of biological terrorism offers our government an unsought but unique opportunity to multiply the impact of federal dollars. Funds for disease surveillance, building the pharmaceutical stockpile, and improving the capacity of our public health system will benefit the United States in responding to biological weapons attack. It will also improve our responses to naturally occurring disease outbreaks, both at home and abroad. We have a rare chance to defend our nation and improve public health for America and the world with the same dollars at the same time. We must take advantage of this opportunity and get others to join. This is a global threat. It will require a global response. The time to begin is now.

Conference Synopsis and Observations

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ABSTRACT

The articles reflecting the proceedings of the first-ever national public health law conference, *Law and the Public's Health in the 21st Century*, make it clear that public health law is the synergistic intersection of public health practices and the law. This article offers, and reflects on, observations organized around five themes expressed at that conference about the present status of public health law. The first is that public health law is indeed in a renaissance, or period of renewal, as evidenced by the rich history of the discipline and the growing body of scholarship. Secondly, legal preparedness, which offers a framework for action, is a critical component of public health preparedness. Third, law can be practiced preventively to positively impact the public's health, but unguided application of the law as a tool is problematic. Fourth, partnerships between public health and the law and among the professionals in the disciplines that touch law and public health are essential to protecting the public's health. Finally, public health law is in an era of extraordinary challenge, but with those challenges comes great opportunity that must be realized if we are to have excellence in public health practice in the 21st century.

The articles reflecting the proceedings of the conference *The Public's Health and the Law in the 21st Century* offer many examples of the close relationship between public health and the law. The importance of public health and law to one another is apparent. It is also apparent that modern public health law is both complex and dynamic. The status of public health law as a discipline merits attention because law has the potential to profoundly affect public health practice;[1–4] the law affects everything from the administrative structure of a public health agency to zoning laws that contribute to healthful behavior to quarantine powers of public health organizations.

This summary of the conference provides the reader with a sense of the wealth of knowledge shared during the conference and the opportunity exposed for law and public health to enter a closer partnership. Observations about the present status of public health law were arranged around five basic themes:

1. Public health law as a discipline is in its renaissance,[5] a renaissance brought about by current world events and the needs of our modern society.
2. Legal preparedness is a critical component of public health preparedness[1] because legal preparedness offers a framework for public health action, not only in emergencies but also in daily practice.
3. Law can be practiced in such a manner as to positively impact the public's health by preventing morbidity and mortality,[6] but there are limitations to this *modus operandi*.
4. Partnerships between public health and the law and among professionals in those disciplines are essential to protecting the public's health.
5. Finally, both public health and public health law face unprecedented challenges along with the opportunities that accompany those challenges.

The following remarks form a synthesis of concepts and ideas about public health law.

The Renaissance of Public Health Law

It has been said before, but it bears repeating-public health law is in its renaissance.[5] While the use of the word *renaissance* might seem high-minded, the renewal that public health law is currently experiencing is indeed unique and major in scope.

Some mistakenly believe that public health is an emerging discipline; in fact, it is not at all new, particularly not here in the United States, where the idea that the law should be used to protect and promote the public's health is found in the Constitution itself. The public's health was recognized as a central purpose of law and government when it was provided that Congress should have the power to tax and spend for the "general Welfare of the United States."[7] Since those beginnings, and perhaps even before, law has continuously played a critical role in the development and promotion of public health in this country.[8] As Moulton, Goodman, Cahill, and Baker recently noted, many examples of United States public health laws to promote the development of public health exist, including such legislation as Title X of the Public Health Service Act, the Food and Drugs Acts, state seat belts laws, and OSHA standards.[1]

Today, public health law is experiencing a "renaissance" because of awareness about the many and important ways that legislation, litigation, and regulation impact the practice of public health law. Much of this awareness is attributable to the current highly political threats to public health resulting from the September 11 terrorist attacks and subsequent events; it is also attributable to a growing public understanding of the role of law in the public's health arising from sometimes controversial attention by the media to issues such as tobacco litigation, tire tread separation litigation and alert systems, drug policies, and firearm violence. The field's renewal as a discipline also seems to stem from a growing interest among academics in cross-disciplinary and inter-disciplinary issues reflective of the growing public awareness of the tension between individual rights and healthy communities.

This renaissance in public health law has been clearly demonstrated in recent firsts, including this national public health law conference, which felt like a homecoming for many of the attendees. At the conference, over 500 professionals from law, medicine, nursing, ethics, academia, anthropology, and government—in all, representing eleven countries—exchanged information and built partnerships relating to public health law. Another first was the *Journal of Law, Medicine & Ethics'* Summer 2002 Symposium on Public Health Law,[5] in which more than 21 articles on the intersection of public health and law were published. In addition to a rising number of articles on the subject, in recent years there have been an unprecedented number of books published on public health law, the authors of many of which were honored at the Millbank Foundation's authors' reception during the Conference. Thus, with the renewed status of public health law comes the opportunity to strengthen each component discipline by improving our understanding of each discipline and their intersections.

Legal Preparedness Is a Critical Component of Public Health Preparedness

Effective public health preparedness requires legal preparedness because legal preparedness creates a legitimate framework for public health action in the event of a crisis. Concurrent sessions, such as "Do We Need a New Law or Regulation?," "Legal Preparedness for Bioterrorism," and others held during the conference highlighted the importance of legal preparedness.

Moulton and Matthews tell us that an effective legal foundation for public health practice must consist of legal authorities, the skills to apply them, and information for those who design and implement public health laws.[9] Stated another way, public health legal preparedness requires that after public health problems and priorities are identified and understood, three things can and should occur:

Conference Sessions	Legal Preparedness		Preventive Mandates	Plenary (P) or Concurrent Session (C)
	Emergency	Infrastructure		
Do We Need a New Law or Regulation?	X	X		C
Legal Preparedness for Bioterrorism	X			C
Preparedness on the Front Line: What's Law Got to Do with It?	X			C
Public Health Emergencies and the Public Health/Managed Care Challenge	X	X		C
The Legal Context of Mosquito Control for West Nile Virus in New York City	X	X		C
Building the Legal Foundation for an Effective Public Health System		X		C
On the Edge of Tomorrow: Fitting Genomics into Public Health Policy		X		C
Will Biomonitoring Change How We Regulate Toxic Chemicals		X		C
Immunization for Seniors			X	C
Health Officers and Legal Counsel: Partners in Prevention	X	X		C
Childhood Immunization: Laws That Work			X	C
The Impact of Law on HIV and STD Prevention			X	C
Immigrant Health: Legal Tools/Legal Barriers		X		C
Graduated Licensing for Teens: Why Everybody's Doing It			X	C
Kids In Cars: Closing Gaps in Child Occupant Restrain Laws			X	C
Protecting our Vulnerable Food Supply	X		X	C
New Approaches to Safe Drinking Water			X	C
Asthma: the Impact of Policies on Breathing Easier			X	C
Fluoridation at 50: What Have We Learned			X	C
Violence Against Women: The State of Batterer Prevention Programs			X	C
Land Use Planning: Why Public Health Must be Involved		X	X	C
Clean Indoor Air: Where, Why and How			X	C
Tobacco Use: The Impact of Prices			X	C
Policy Tools for the Childhood Obesity Epidemic			X	C
The Dimensions of Public Health Law Research		X		C
Perspectives on Legal Strategies to Prevent Workplace Violence			X	C
When the Law Is Good Medicine		X	X	P
Partners in Public Health Law: Elected Officials, Health Directors, and Attorneys		X		P
How Do We Translate Science into Public Health Policy and Law				P
New Perspectives on Litigation and the Public's Health				P
The Future of Public Health Preparedness	X	X		P

1. The need and roles for laws or judicial action should be identified;
2. The laws or judgments affecting such problems and priorities must be enforced; and
3. The legal bases for action should be monitored or revised as the public's health demands.

Laws provide a framework for action in the event of a public health emergency, but they also provide a framework for action and responsibility in promoting the public's health on a day-to-day basis. Complete legal preparedness includes the existence of laws that create a sound public health infrastructure. Depending on the specific public health priority or problem, the need and role for laws or judicial or administrative action may vary widely; nonetheless, appropriate legal and public health bases for action must be identified to ensure that when action is necessary, it can be taken.

In some cases, specific existing authorities that give governments and individuals the power to act in an emergency may require modernization to serve as effective bases for action. Many of the public health laws in this country are antiquated, and many are disease-based[2,3] and therefore do not offer public health officials the flexibility necessary to respond to emerging threats. Moreover, while the recently developed Model State Emergency Health Powers Act[10] offers some guidance, there is still a great deal to be done to ensure that appropriate legal authorities are in place around the country.

Even with effective and modern authorities in place, good public health legal preparedness still requires people who understand and will execute those authorities faithfully.[9] Information and networking for those who make, work within, or interpret public health laws must be available.[1] Also, because there is a subtle but complex relationship between federalism and individual rights,[11] persons exercising public health authorities must be well versed in those complexities.

Finally, legal preparedness is a continuous process. It requires a constant state of awareness, and the legal bases for action in public health must be continuously monitored and revised. Such monitoring and revision will prevent the likelihood of confronting future public health crises with outdated public health legal authorities. Because effective public health preparedness requires legal preparedness, public health and legal practitioners must work together to create a strategy to achieve their interrelated goals. Full preparedness should be one of the primary goals of public health.[1]

Practicing Law to Prevent Illness, Disease, and Injury

Many types of law can impact the public's health-laws that are intended to mitigate or enhance public health efforts, laws that create public health infrastructure, and laws that have indirect or unintended public health consequences. However, laws that are written and enforced to proactively prevent harm to the public health by preventing illness, disease, or injury are the most easily recognizable type of public health law and are now more than ever becoming a tool for practicing and promoting public health. This type of law, sometimes referred to as "preventive law," most often takes the form of a legislative mandate, such as compulsory vaccinations for school attendance, fluoridation standards for water, housing codes, or food safety standards. Proactive efforts to protect the public's health through legal means can also occur through litigation, such as the many recent lawsuits against the tobacco industry or a well-developed administrative rule or procedure, such as the EPA's standards for environmental lead levels.[12]

During the conference, fifteen concurrent sessions showcased the public health achievements made possible by laws with the specific intent to prevent illness, disease, or injury. Sessions included "Graduated Licensing for Teens: Why Everybody's Doing It" and "Kids In Cars: Closing Gaps in Child Occupant Restraint Laws," both of which highlighted opportunities for public health officials to reduce injuries by placing mandates on populations that have not historically been covered by these types of laws.

While preventive law offers the clearest and most visible opportunity for law to affect the public's health and for public health to inform the law, it is by no means the only kind of law that impacts public health. Public health law is not merely the study of public benefit laws, the statutes and regulations of the states, territories and federal government, or merely litigation. Also crucial is the richness of the intersection of other kinds of law, such as administrative law, constitutional law, contract law, and tort law engaged through legislation, litigation, and policy, with the public's health as the direct or indirect subject matter.

While the law can be a tool for prevention, it is just that—a tool. It is only as effective as those who wield it. Because the focus of litigation is usually punitive and for monetary compensation, litigation that often has an impact on health and public health does not always have a positive public health impact, nor is the impact as certain as a plaintiff's attorneys may suggest. Sometimes, even the most well intended statutes can have unintended public health consequences. It recently became apparent that laws in some states meant to eliminate drugs in the school environment were also not allowing the students to self-medicate with inhalers; hence, these laws prevented children from effectively managing their asthma (see "Asthma: The Impact of Policies on Breathing Easier" in this issue).

Jan Schlitchman, the subject of *A Civil Action*, has observed in his address to the conference that

"…like every good carpenter, you don't blame your tools for bad work, and it really in the end amounts to something else; something else we have to think about to guide our use of these tools" (see "New Perspectives on Litigation and the Public's Health" in this issue.) As we develop law as a tool for actively protecting and promoting the public's health, solid public health priorities and ethics must guide our actions. Law cannot simply be assumed to be a good in and of itself within public health; instead, it must be carefully crafted to improve the public's health.

Partnerships Between Law and Public Health Are Essential to Protecting the Public's Health

The law should be thought of not as something merely reactionary, nor as something limited to the regulation of healthcare; instead, the law should be thought of as an equal, active partner in public health, while public health is an equal and active partner in the law. A symbiotic relationship, or synergy, between public health and the law is essential to modern public health practice.

Partnerships between law and public health are not a zero-sum game. Professionals from both disciplines can gain from creating opportunities to bring the two fields closer. Without partnerships, the risks to public health are grave. For example, unless the interaction between public health and policymakers is improved, we face the continued risk of legislators' enacting laws without adequate information about how their actions will affect public health, or we risk public health officials' having inadequate legal support to reduce threats to the population's health.

Indeed, many obstacles to creating effective partnerships exist. However, the opportunities for partnerships are plentiful, and the results may shape public health practice far into the future. For example, schools of law and schools of public health might continue to seek opportunities to share faculty and educate each other's students,[4,13] and litigators might continue to seek opportunities to share the results of their labor as they did when the State of Minnesota helped make its tobacco litigation documents available around the world for use in lawsuits that would otherwise be unheard (see Michael Ceresi's comments in "New Perspectives on Litigation and the Public's Health" in this issue).

Good advocates are crucial to protecting and improving public health.[8,9] Lawyers as advocates can effectively shape public health policy if they possess the skills necessary to make contacts within the public health and political arenas. Through partnerships, legal professionals, government officials, and public health professionals have the potential to achieve more than would be possible acting alone.

Conclusion: An Era of Unprecedented Challenge and Opportunity

The events of September 11th and the subsequent anthrax attacks made even more recognizable the need for an effective public health system[11] and even more apparent the challenges of ensuring an effective public health system. These challenges present enormous opportunity for the field of public health law.

Challenges

The challenges faced by public health law include the latest developments that public health must respond to, the changing role of lawyers in public health, changes in the disciplines of law and public health themselves, and global change.

"Public health is everywhere and always contingent,"[14] meaning that public health is constantly in demand and must continuously respond to the changing health needs of the population. However, public health faces special challenges in the 21st century. They include emerging infectious diseases such as hemorrhagic fevers and Hantavirus, the potential for another influenza pandemic, the growing burden of chronic diseases such as diabetes, and the growing health disparities around the world (see welcoming remarks of Dr. Julie Gerberding in this issue). Public health law must also address the obstacles encountered

by such interdisciplinary features as professional bias, differences in communication modes, and time limitations. There is a need for concerted reciprocal education in both schools of law and schools of public health[4] to achieve a joint understanding of how to proceed and work together.

The challenges also include recognizing the changing role of lawyers within the U.S. public health arena. Conference moderator Gene Matthews has said, "If law is the tool of public health, and lawyers have to provide the advice and guide us in the operations and programs and implementation, then we're [lawyers] stepping out of our historical role as technicians." At the same time, the legal profession is being changed by factors outside the public health arena, including recent federal challenges to the nature of the attorney-client privilege.

Internationally, the challenges are even greater. We live in a dynamic world of global interdependency and political, religious, and ideological differences and a growing body of international law together with an increasing complexity of international politics. These factors, combined with new threats of terrorism and bioterrorism, make the challenges faced by public health and public health law in this new century unlike those of the last century.

Opportunities

Clearly, the many challenges facing public health have legal components. The current status of public health law could be summarized in one word: opportunity.

Dr. Julie Gerberding, the Director of the Centers for Disease Control and Prevention (CDC), stated that the conference, representative in many ways of public health law as a whole, was a conciliance, or the bringing together of ideas from a wide and disparate set of disciplines (see Dr. Gerberding's welcoming remarks in this issue). This unification of diversity is perhaps the most important opportunity public health law has to offer, because when a variety of perspectives and ideas are brought together, there is potential not only for learning but also for self-reflection. One important opportunity that resulted from the conference and its participants was the beginning of discussions about the formation of a public health law association.

A unique opportunity to capitalize on the current public awareness of and government interest in public health now exists because of events such as terrorism, emerging illnesses, and legal developments. The opportunity includes latitude to grow partnerships and develop the role of law and lawyers in public health. It also includes involving individuals with experience in public health in roles that have traditionally been the domain of those with legal training, such as participating in the drafting of laws and regulations, updating public health authorities, establishing public health ethics, and more effectively using law to prevent illness, disease, or injury.

Public health practice in the 21st century will turn on how these opportunities are seized upon and the extent to which public health practice seeks to gain from the synergy between public health and law. There is always a hope that from terrible events, there will be some good. If from the horrors of the fall of 2001 we focus on unified, functional, and vibrant collaborative efforts between public health and law, at least we will have achieved some good. We have great faith—especially as a result of this public health law conference and the large attendance of public health practitioners, government officials, lawyers, academicians and representatives from numerous other disciplines—that this potential will be realized and that our future contains limitless opportunity.

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Appendix A
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The Centers for Disease Control Public Health Law Team

Appendix B

Collaborating Conference Organizations and Centers for Disease Control and Prevention Programs

Alfred P. Sloan Foundation

All Kids Count

American Bar Association Standing Committee on Law and National Security

Association of State and Territorial Health Officials

Center for Law and the Public's Health, Johns Hopkins University and Georgetown University

Emory University Rollins School of Public Health

Hirsh Health Law and Policy Program, George Washington University School of Public Health and Health Services

Institute for Bioethics, Health Policy and Law, University of Louisville

Milbank Memorial Fund

National Association of Attorneys General

National Association of County and City Health Officials

National Association of Local Boards of Health

National Conference of State Legislatures

National Strategy Forum

Northeastern University School of Law and Tufts University School of Medicine JD/MPH Dual Degree Program

Turning Point Public Health Statute Modernization National Collaborative

The following Centers, Institutes, and Offices at the Centers for Disease Control and Prevention:

CDC Office of the Director

Office of General Counsel

Office of Global Health

National Center for Infectious Diseases

National Center for Environmental Health

National Center for Chronic Disease Prevention and Health Promotion

National Institute for Occupational Safety & Health

Epidemiology Program Office

Public Health Practice Program Office

Agency for Toxic Substances and Disease Registry

National Center for Injury Prevention and Control

National Immunization Program

National Center for HIV, STD, and TB Prevention

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FEATURING

- Advanced search capabilities to help navigate the site
- Chronological and subject indices of *AJLM* and *JLME*
- Introductions to past journal articles
- Streaming audio and video presentations from past conferences
- Updates and information on ASLME's funded research projects
- Full text of all Mayday Scholars' papers on effective pain treatment including the "Pain Relief Act"
- Information about upcoming ASLME-sponsored conferences
- Recent developments in health law and medicine
- Over 500 annotated links arranged by subject
- Submission guidelines for *AJLM* and *JLME*
- Sign up for free as a webmember and get access to the full text of the article of the month from *AJLM* or *JLME*

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American Society of Law, Medicine & Ethics

Calendar of Professional Education Events

Genetic Bonds and Family Law: The Challenge of DNA Parentage Testing

March 27-28, 2003
New Orleans Louisiana

Along with The Institute for Bioethics, Health Policy and the Law at the University of Louisville and the Hastings Center, ASLME will jointly sponsor a one day conference that will examine the ethical, legal, and social implications of DNA-based testing outside the context of the criminal law. A special focus will be on implications for families.

27th Annual Health Law Teachers Conference

June 5-7, 2003
Widener University School of Law
Wilmington, Delaware

Widener University School of Law will co-sponsor this two day conference intended for professionals who teach law or bioethics in schools of law, medicine, public health, health care administration, pharmacy, nursing, and dentistry. The program is designed to provide participants with updates on issues at the forefront of law and medicine and to provide them with the opportunity to share strategies, ideas, and materials.

The Public's Health and the Law in the 21st Century

June 16-18, 2003
Sheraton Colony Square Hotel
Atlanta, Georgia

For the second year in a row, the Centers for Disease Control and Prevention (CDC) and ASLME will co-sponsor a three day conference to explore the vital role the law plays in protecting the public's health now and in the future.

The Pitts Lectureship- When People Attack People: Policy and Ethics of Violence

September 19-20, 2003
Charleston, South Carolina

The Medical University of South Carolina and ASLME will co-sponsor the Pitts Leadership lecture.

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PAIN & THE LAW

www.painandthelaw.org

Developed by Saint Louis University and the American Society of Law, Medicine & Ethics under a grant from the Mayday Fund

Pain and the Law represents the Internet's most comprehensive collection of materials and commentary on the legal and professional issues raised by the treatment of pain.

The issues surrounding the treatment of people in pain are highly controversial. The drugs used to treat serious pain include opioids and frequently diverted prescription pain medications such as OxyContin. And medical professionals have differing opinions and training regarding serious pain. Uncertainties about the complex legal and regulatory environments influencing the treatment of pain have compounded the problem, leading to incidences of both overmedication and undermedication.

Pain and the Law is a comprehensive resource with information on the many legal issues involved in pain management. The site includes hundreds of links to primary sources such as federal legislation and court decisions, as well as commentary from leaders in the field.

Some features of the site include breaking news, links to related sources, video from pain management conferences, and a free electronic newsletter.

Highlights:

- The Statutes & Regulations section, which discusses the effects of legislation and professional standards both as they promote and discourage treatment of pain, and the tension between promotion of effective palliative care and controlled substance legislation. This section includes links to the text of many state and national statutes – both proposed and enacted – including the Model Pain Relief Act.
- The Malpractice & Civil Actions section includes links to case decisions regarding malpractice claims for undermedication, overmedication, failure to refer, and failure to obtain informed consent and commentary on these claims.
- Criminal prosecution is covered in the Palliative Care & Criminal Action section, and includes prosecution of caregivers for both overtreatment and undertreatment of pain, the links between palliative care and physician assisted suicide, and prosecution arising from violation of controlled substance laws. Specific cases and discussion of OxyContin abuse and the use of medical marijuana are included in the discussion of controlled substance prosecution.

- The Entitlement Programs section deals with pain patients' access to Social Security benefits, Medicare and Medicaid, Worker's Compensation, reimbursement under private insurance, and protection under the Americans with Disabilities Act, highlighting the difficulty in assessing and measuring pain.

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